



**Australian Government**

**Department of Health  
and Aged Care**



# Schedule of Pharmaceutical Benefits

Section 100 – Items Available under Special Arrangement - Volume 2

**Effective 1 April 2025**

This Schedule is also available at [www.pbs.gov.au](http://www.pbs.gov.au)



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

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# Fees, Patient Contributions and Safety Net Thresholds

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

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

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

# Summary of Changes

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

## Prescriber Bag

### Deletions

#### Deletion – Item

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

## General Pharmaceutical Benefits

### Additions

#### Addition – Item

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

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

**Addition – Brand**

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

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

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

**Addition – Equivalence Indicator**

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

**Addition – Note**

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

**Addition – Restriction**

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

## Deletions

### Deletion – Item

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

### Deletion – Brand

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

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

**Deletion – Equivalence Indicator**

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

**Deletion – Note**

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

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

## Alterations

### Alteration – Note

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



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

**Alteration – Restriction**

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

**Alteration – Restriction Level**

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

**Alteration – Manufacturer Code**

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

**Supply Only**

**Supply Only – Period Commencing**

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

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**Supply Only – Period Ending**

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

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

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



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

### 1 July 2025

#### Deletion – Brand

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

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

## Palliative Care

### Deletions

#### **Deletion – Item**

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

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

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

#### **Deletion – Note**

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

## Advance Notices

**1 May 2025**

#### **Deletion – Brand**

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

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## Highly Specialised Drugs Program (Private Hospital)

### Additions

#### Addition – Item

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

#### Addition – Brand

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

### Deletions

#### Deletion – Brand

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

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

## Alterations

### **Alteration – Note**

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

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

## Advance Notices

**1 June 2025**

### Deletion – Brand

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

**1 July 2025**

### Deletion – Brand

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

### Additions

#### Addition – Item

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



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

**Addition – Brand**

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

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

**Deletions**

**Deletion – Brand**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Alterations**

**Alteration – Note**

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

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

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

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

## Advance Notices

**1 June 2025**

### Deletion – Brand

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

**1 July 2025**

### Deletion – Brand

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

### Deletions

#### Deletion – Brand

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

#### Supply Only – Period Commencing

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

## Advance Notices

**1 May 2025**

### Deletion – Brand

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

### Deletions

#### **Deletion – Brand**

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

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

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

### Alterations

#### **Alteration – Restriction**

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

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

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

### Advance Notices

#### **1 May 2025**

#### **Deletion – Brand**

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

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



# About the Schedule

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

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

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

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

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

## Symbols and Abbreviations Used in the Schedule

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

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## Restricted Benefits

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

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

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

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

# Guidelines and General Statements

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

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

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

### Treatment criteria:

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

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

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

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

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

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

### HEPATITIS C - NON-CIRRHOTIC PATIENTS

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

### HEPATITIS C – CIRRHOTIC PATIENTS

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

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

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

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



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

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# Highly Specialised Drugs Program (Private Hospital)

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## ALIMENTARY TRACT AND METABOLISM

### OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

#### OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

*Various alimentary tract and metabolism products*

#### ▪ TEDUGLUTIDE

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

##### **Authority required**

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment - balance of supply

##### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

##### **Clinical criteria:**

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug under the initial treatment restriction to complete the maximum duration of 12 months of initial treatment, **AND**
- The treatment must provide no more than the balance of up to 12 months of treatment.

#### **teduglutide 5 mg injection [28 vials] (& inert substance diluent [28 x 0.5 mL syringes], 1 pack**

11812Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	19759.27	Revestive [TK]

#### ▪ TEDUGLUTIDE

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

##### **Authority required**

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Continuing treatment

##### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

##### **Clinical criteria:**

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have a reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline; OR
- Patient must have, as a patient yet to turn 18 years of age, a reduction in the mean weekly parenteral support volume of at least 20% (mL per kg of body weight) relative to baseline; OR
- The treatment must be resuming after a break in therapy, but before the break in therapy occurred, a reduction in parenteral support relative to baseline had been occurring to an extent as stated as above.

Refer to the measurement(s) stated in the Initial treatment authority application for the baseline dependence on parenteral support. Determine the current mean use per week of parental support in days (for a patient of any age) and/or the mean volume per week in mL per kg (for a patient yet to turn 18 years of age). State these values in this authority application.

The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.

The current mean weekly parenteral support volume is calculated as the mean mL per kg of body weight of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.

From 1 September 2021

Where the mean weekly volume of parenteral support in terms of mL per kg of body weight for 4 consecutive weeks has not been stated in an Initial treatment authority application for a patient yet to turn 18 years of age, provide in this authority application both:

- (i) a known or estimated retrospective baseline value that would have applied to the patient immediately before commencing treatment with this drug, and
- (ii) the current value (observed over a 4 week timeframe)

Provide these values for a child only where mean weekly volume is to be used as an alternative response assessment to mean days of parenteral support per week. Otherwise, continue to use mean days per week.

Where treatment is resuming after a break in treatment with this drug, state parenteral support days/volume values as occurring prior to the break instead of current values.

A patient who has turned 18 years of age since their last authority application may be assessed for response using either the mean number of days of parenteral support or mean volume of parenteral support. Any subsequent authority application after this application must be assessed using the mean number of days of parenteral support.

Patients who do not meet the clinical criteria with respect to demonstrating the minimum reduction in parenteral support must permanently discontinue PBS subsidy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### teduglutide 5 mg injection [28 vials] (& inert substance diluent [28 x 0.5 mL syringes], 1 pack

11806J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19759.27	Revestive [TK]

#### ▪ TEDUGLUTIDE

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

#### **Clinical criteria:**

- Patient must have short bowel syndrome with intestinal failure following major surgery, **AND**
- Patient must have a history of dependence on parenteral support for at least 12 months, **AND**
- Patient must have received a stable parenteral support regimen for at least 3 days per week in the previous 4 weeks, **AND**
- Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years, **AND**
- The treatment must not exceed 12 months under this restriction, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either:

- (i) for a patient of any age, the mean number of days of parenteral support per week
- (ii) for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg.

Determine the mean over any given 4 week period prior to this authority application. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i).

Assessment of treatment response/non-response in the 'Continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.

A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack**

11795T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	19759.27	Revestive [TK]

▪ **BLOOD AND BLOOD FORMING ORGANS**

▪ **ANTIHEMORRHAGICS**

**VITAMIN K AND OTHER HEMOSTATICS**

*Other systemic hemostatics*

▪ **AVATROMBOPAG**

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either romiplostim or eltrombopag to this drug under the Balance of Supply/Change of Therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

## BLOOD AND BLOOD FORMING ORGANS

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
  - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
  - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
  - Patient must be changing therapy from romiplostim or eltrombopag to this drug for this condition, **AND**
  - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with romiplostim or eltrombopag may change to avatrombopag under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### avatrombopag 20 mg tablet, 30

13317X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2649.73	Doptelet [ZO]

### ▪ ELTROMBOPAG

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

### **Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.



The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**eltrombopag 25 mg tablet, 28**

14115X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	3	..	*3733.02	Revolade [NV]

▪ **ELTROMBOPAG**

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

**Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than  $50 \times 10^9/L$ , haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than  $1 \times 10^9/L$  for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

**eltrombopag 25 mg tablet, 28**

14119D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*3733.02	Revolade [NV]

▪ **ELTROMBOPAG**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

**Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### eltrombopag 50 mg tablet, 28

14107L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	3	..	*7417.38	Revolade [NV]

#### ■ ELTROMBOPAG

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

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

#### **Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**

- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.

Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than  $50 \times 10^9/L$ , haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than  $1 \times 10^9/L$  for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

### eltrombopag 50 mg tablet, 28

14143J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*7417.38	Revolade [NV]

#### ■ ELTROMBOPAG

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Severe aplastic anaemia

Treatment Phase: First line treatment

#### **Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

#### Authority required

Severe aplastic anaemia

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - First line treatment

#### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**eltrombopag 25 mg tablet, 28**

14136B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*3733.02	Revolade [NV]

▪ **ELTROMBOPAG**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe aplastic anaemia

Treatment Phase: First line treatment

**Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Severe aplastic anaemia

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - First line treatment

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

## BLOOD AND BLOOD FORMING ORGANS

### eltrombopag 50 mg tablet, 28

14127M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*7417.38	Revolade [NV]

#### ■ ELTROMBOPAG

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

**Note** Special Pricing Arrangements apply.

##### Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

##### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

##### Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

##### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**

• The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

##### Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
  - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
  - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
  - Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
  - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**eltrombopag 25 mg tablet, 28**

5827Q	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1276.79	Revolade [NV]

▪ **ELTROMBOPAG**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health

## BLOOD AND BLOOD FORMING ORGANS

Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

### **Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **eltrombopag 50 mg tablet, 28**

5828R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2504.91	Revolade [NV]

### ▪ ROMIPILOSTIM

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

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either eltrombopag or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
- Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
- Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
- Patient must be changing therapy from eltrombopag or avatrombopag to this drug for this condition, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.

Patients receiving treatment with eltrombopag or avatrombopag may change to romiplostim under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**romiplostim 250 microgram injection, 1 vial**

9697J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	522.55	Nplate [AN]

**romiplostim 500 microgram injection, 1 vial**

9699L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1036.44	Nplate [AN]

**ANTIANEMIC PREPARATIONS**  
**OTHER ANTIANEMIC PREPARATIONS**  
*Other antianemic preparations*

**DARBEPOETIN ALFA**

**Authority required (STREAMLINED)**

**9688**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

6320P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*242.01	Aranesp [AN]

**darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL pen device**

6492Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1699.79	Aranesp SureClick [AN]

**darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6326Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1699.83	Aranesp [AN]

HSD (Private)



**darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL pen device**

6493R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*2508.83	Aranesp SureClick [AN]

**darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

6365B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2508.85	Aranesp [AN]

**darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL pen device**

6488L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*448.11	Aranesp SureClick [AN]

**darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6321Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*448.11	Aranesp [AN]

**darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

6322R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*609.87	Aranesp [AN]

**darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL pen device**

6489M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*738.35	Aranesp SureClick [AN]

**darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

6323T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*738.39	Aranesp [AN]

**darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6324W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*910.85	Aranesp [AN]

**darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL pen device**

6490N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1067.31	Aranesp SureClick [AN]

**darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

6325X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1067.31	Aranesp [AN]

**darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL pen device**

6491P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1389.55	Aranesp SureClick [AN]

**darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

6438W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1389.49	Aranesp [AN]

▪ **EPOETIN ALFA**

**Authority required (STREAMLINED)**

**9688**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

6251B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*191.69	Epex 1000 [JC]

**epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes**

6207Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1290.11	Epex 10000 [JC]

## BLOOD AND BLOOD FORMING ORGANS

### epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

6204M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*347.33	Eprex 2000 [JC]

### epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

6434P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2490.89	Eprex 20,000 [JC]

### epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

6205N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*445.67	Eprex 3000 [JC]

### epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

6206P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*565.21	Eprex 4000 [JC]

### epoetin alfa 40 000 units/mL injection, 1 mL syringe

6339P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*830.39	Eprex 40,000 [JC]

### epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

6302Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*701.53	Eprex 5000 [JC]

### epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

6303R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*831.15	Eprex 6000 [JC]

### epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

6305W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1074.39	Eprex 8000 [JC]

## ■ EPOETIN BETA

### Authority required (STREAMLINED)

**9688**

Anaemia associated with intrinsic renal disease

#### Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

### epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes

6485H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1290.03	NeoRecormon [RO]

### epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes

6480C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*347.29	NeoRecormon [RO]

### epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

6481D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*445.65	NeoRecormon [RO]

### epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes

6482E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*565.17	NeoRecormon [RO]

### epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes

6483F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*701.49	NeoRecormon [RO]

### epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes

6484G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*831.09	NeoRecormon [RO]

## ■ EPOETIN LAMBDA

### Authority required (STREAMLINED)

**9688**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

9685R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*243.95	Novicrit [SZ]

**epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes**

9595B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1644.63	Novicrit [SZ]

**epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes**

9686T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*444.01	Novicrit [SZ]

**epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

9687W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*570.47	Novicrit [SZ]

**epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

9688X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*724.13	Novicrit [SZ]

**epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

9588P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*899.39	Novicrit [SZ]

**epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

9590R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1065.33	Novicrit [SZ]

**epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes**

9593X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1367.27	Novicrit [SZ]

**▪ METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA****Authority required (STREAMLINED)****9688**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 0.3 mL syringe**

9574X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*238.51	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 0.3 mL syringe**

9575Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*391.75	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 0.3 mL syringe**

9576B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*566.49	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 0.3 mL syringe**

9577C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*730.09	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 0.3 mL syringe**

9578D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*843.91	Mircera [RO]

## CARDIOVASCULAR SYSTEM

### methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 0.3 mL syringe

9579E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1200.57	Mircera [RO]

### methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 0.6 mL syringe

9580F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2039.97	Mircera [RO]

## ■ CARDIOVASCULAR SYSTEM

## ■ ANTIHYPERTENSIVES

### OTHER ANTIHYPERTENSIVES

*Antihypertensives for pulmonary arterial hypertension*

## ■ AMBRISENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

#### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

#### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
- (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

## CARDIOVASCULAR SYSTEM

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### ambrisentan 10 mg tablet, 30

9649W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1430.20	<sup>a</sup> Ambrisentan Viatris [AL] <sup>a</sup> PULMORIS [XT]	<sup>a</sup> Cipla Ambrisentan [ZU] <sup>a</sup> Volibris [ZE]

### ambrisentan 5 mg tablet, 30

9648T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1430.20	<sup>a</sup> Ambrisentan Viatris [AL] <sup>a</sup> PULMORIS [XT]	<sup>a</sup> Cipla Ambrisentan [ZU] <sup>a</sup> Volibris [ZE]

## ■ AMBRISENTAN

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

### Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- a completed authority prescription form; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- for why fewer than 3 tests are able to be performed on clinical grounds;
- why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

**Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.



The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**ambrisentan 10 mg tablet, 30**

12180C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1430.20	<sup>a</sup> Ambrisentan Viatris [AL] <sup>a</sup> PULMORIS [XT]	<sup>a</sup> Cipla Ambrisentan [ZU] <sup>a</sup> Volibris [ZE]

**ambrisentan 5 mg tablet, 30**

12201E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1430.20	<sup>a</sup> Ambrisentan Viatris [AL] <sup>a</sup> PULMORIS [XT]	<sup>a</sup> Cipla Ambrisentan [ZU] <sup>a</sup> Volibris [ZE]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

**Clinical criteria:**

- Patient must be receiving PBS-subsidised treatment with this PAH agent, **AND**
- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**bosentan 62.5 mg tablet, 60**

12143D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	184.74	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan Mylan [AF]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan RBX [RA]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

HSD (Private)

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.

**bosentan 62.5 mg tablet, 60**

12139X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	184.74	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan Mylan [AF]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan RBX [RA]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of the rapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of the rapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**bosentan 125 mg tablet, 60**

6430K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	184.74	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan GH [GQ] <sup>a</sup> Bosentan RBX [RA]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan Mylan [AF]

**bosentan 62.5 mg tablet, 60**

6429J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	184.74	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan Mylan [AF]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan RBX [RA]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.
- (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.
- (5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

#### **Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

#### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where multiple strengths of this drug are sought, the combined number of repeats sought for each strength should not exceed 5. If the optimal strength is still to be determined by the end of the initial PBS supply, prescribers are reminded that further supplies of the optimal strength may be obtained via the Continuing treatment listing via a telephone/online authority application.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**bosentan 62.5 mg tablet, 60**

12148J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	184.74	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan Mylan [AF]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan RBX [RA]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
- (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)). Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

### **Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

### **Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where multiple strengths of this drug are sought, the combined number of repeats sought for each strength should not exceed 5. If the optimal strength is still to be determined by the end of the initial PBS supply, prescribers are reminded that further supplies of the optimal strength may be obtained via the Continuing treatment listing via a telephone/online authority application.



**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**bosentan 125 mg tablet, 60**

12146G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	184.74	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan GH [GQ] <sup>a</sup> Bosentan RBX [RA]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan Mylan [AF]

HSD (Private)

## ▪ EPOPROSTENOL

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

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)  
 Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)  
 Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)  
 Treatment Phase: Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

**Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## epoprostenol 1.5 mg injection, 1 vial

10129D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*1828.47	Veletri [JC]

## epoprostenol 500 microgram injection, 1 vial

10111E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*1046.97	Veletri [JC]

## ■ ILOPROST

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

### Authority required

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

### Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class III drug and toxins induced PAH, or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

### Treatment criteria:

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
- (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)  
 Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)  
 Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis



**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

**Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost  
 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost  
 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application,

**AND**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

6456T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	372.24	Ventavis [BN]

▪ **MACITENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH,

**AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.
- (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.
- (5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**macitentan 10 mg tablet, 30**

10134J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2644.69	Opsumit [JC]

▪ **MACITENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

**Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**macitentan 10 mg tablet, 30**

12135Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2644.69	Opsumit [JC]

▪ **RIOCIGUAT**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be at least 18 years of age.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

(a) Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 90 days after start of full anticoagulation; and

(b) A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

RHC demonstrating a PVR of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be documented in the patient's medical records.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the results from the 3 tests below, to establish baseline measurements, where available:

- (i) RHC composite assessment, and
- (ii) ECHO composite assessment, and
- (iii) 6 Minute Walk Test (6MWT); and

(b) confirmation of evidence of inoperable CTEPH including the pulmonary vascular resistance (PVR) value, a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or

(c) confirmation of evidence of recurrent or persistent CTEPH including the PVR value and the date that pulmonary endarterectomy was performed; or

(d) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, the expected test combination, in descending order of preference is:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, the expected test combinations, in descending order of preference is:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be documented in the patient's medical records.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

### **Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

### **Population criteria:**

- Patient must be at least 18 years of age.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be documented in the patient's medical record with each continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be documented in the patient's medical records.

The test results conducted for continuing treatment must be no more than 2 months old at the time of application.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.



**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be at least 18 years of age.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**riociguat 500 microgram tablet, 42**

11009K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

**riociguat 1 mg tablet, 42**

10990K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

**riociguat 1.5 mg tablet, 42**

10974N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

**riociguat 2 mg tablet, 42**

11012N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

**riociguat 2.5 mg tablet, 42**

10985E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

■ **RIOCIGUAT**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician with expertise in the management of PAH, **AND**
- Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
- (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

### **Clinical criteria:**

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions. Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**riociguat 500 microgram tablet, 42**

11031N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

**riociguat 1 mg tablet, 42**

11028K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

**riociguat 1.5 mg tablet, 42**

11046J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

**riociguat 2 mg tablet, 42**

11045H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

**riociguat 2.5 mg tablet, 42**

11052Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1680.49	Adempas [BN]

▪ **SELEXIPAG**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

HSD (Private)

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial treatment - dose titration

**Clinical criteria:**

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Population criteria:**

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

**selexipag 200 microgram tablet, 140**

12241G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	8098.67	Upravi [JC]

▪ **SELEXIPAG**

- Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** No increase in the maximum quantity or number of units may be authorised.
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.
- Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.
- Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH
  - Heritable PAH
    - BMPR2 mutation
    - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
    - Other mutations
  - Drugs and toxins induced PAH
  - PAH associated with:
    - Connective tissue disease
    - Human immunodeficiency virus (HIV) infection
    - Portal hypertension
    - Congenital heart disease
    - Schistosomiasis

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial treatment - dose titration

**Clinical criteria:**

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Population criteria:**

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.  
A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.  
For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.  
PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.  
PAH (WHO Group 1 pulmonary hypertension) is defined as follows:  
(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or  
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

**selexipag 800 microgram tablet, 60**

12253X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3498.67	Upravi [JC]

▪ **SELEXIPAG**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment following dose titration

**Clinical criteria:**

- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- Patient must have completed the dose titration phase, **AND**
- The treatment must not be as monotherapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Population criteria:**

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.  
Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.  
A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.  
For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.  
PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.  
PAH (WHO Group 1 pulmonary hypertension) is defined as follows:  
(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

HSD (Private)

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

**selexipag 200 microgram tablet, 60**

12242H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3498.67	Uptravi [JC]

**selexipag 400 microgram tablet, 60**

12260G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3498.67	Uptravi [JC]

**selexipag 600 microgram tablet, 60**

12248P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3498.67	Uptravi [JC]

**selexipag 800 microgram tablet, 60**

12246M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3498.67	Uptravi [JC]

**selexipag 1 mg tablet, 60**

12245L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3498.67	Uptravi [JC]

**selexipag 1.2 mg tablet, 60**

12257D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3498.67	Uptravi [JC]

**selexipag 1.4 mg tablet, 60**

12251T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3498.67	Upravi [JC]

**selexipag 1.6 mg tablet, 60**

12264L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3498.67	Upravi [JC]

▪ **SILDENAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Clinical criteria:**

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:

- Connective tissue disease
- Human immunodeficiency virus (HIV) infection
- Portal hypertension
- Congenital heart disease
- Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)). Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

### **Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **sildenafil 20 mg tablet, 90**

9605M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	108.48	<sup>a</sup> Revatio [UJ] <sup>a</sup> Sildenafil PHT APOTEX [TY]	<sup>a</sup> SILDATIO PHT [RW] <sup>a</sup> Sildenafil Sandoz PHT 20 [SZ]



▪ **SILDENAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

### **Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost  
 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

### **Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

### **Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost  
 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

### **Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application,

**AND**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**sildenafil 20 mg tablet, 90**

12138W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	108.48	<sup>a</sup> Revatio [UJ] <sup>a</sup> Sildenafil PHT APOTEX [TY]	<sup>a</sup> SILDATIO PHT [RW] <sup>a</sup> Sildenafil Sandoz PHT 20 [SZ]

▪ **TADALAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Clinical criteria:**

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
- (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tadalafil 20 mg tablet, 56**

1304P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	503.23	<sup>a</sup> Adcirca [LY] <sup>a</sup> TADALIS 20 [LR]	<sup>a</sup> Tadalca [CR]

▪ **TADALAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Clinical criteria:**

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

HSD (Private)

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tadalafil 20 mg tablet, 60**

14229X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	538.56	Tadalafil 20 [LR]

▪ **TADALAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

## **Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**



- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**tadalafil 20 mg tablet, 56**

12150L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	503.23	<sup>a</sup> Adcirca [LY]	<sup>a</sup> Tadalca [CR]
					<sup>a</sup> TADALIS 20 [LR]	

▪ **TADALAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

- (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:
- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
  - (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

### **Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

#### **Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

#### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

#### **tadalafil 20 mg tablet, 60**

14240L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	538.56	Tadalafil 20 [LR]

## DERMATOLOGICALS

## ANTIPSORIATICS

### ANTIPSORIATICS FOR SYSTEMIC USE

*Psoralens for systemic use*

## METHOXSALEN

**Caution** This drug is for ex vivo administration and must not be injected directly into the patient.

**Note** The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

#### **Authority required (STREAMLINED)**

**10989**

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**

- Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment

**methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials**

12173Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.08	5	..	*225.97	Uvadex [TQ]

▪ **METHOXSALEN**

**Caution** This drug is for ex vivo administration and must not be injected directly into the patient.

**Note** The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

**Authority required (STREAMLINED)**

**10971**

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR
- Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

**Population criteria:**

- Patient must be aged 18 years or over.

**methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials**

12162D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.17	6	..	*443.27	Uvadex [TQ]

▪ **METHOXSALEN**

**Caution** This drug is for ex vivo administration and must not be injected directly into the patient.

**Note** Up to 2 additional repeats to that stated in this listing may be sought.

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

**Authority required (STREAMLINED)**

**12567**

Chronic graft versus host disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both: (i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment, **AND**
- Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition, **AND**
- Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse.

**methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials**

12839R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.17	..	..	*443.27	Uvadex [TQ]

**▪ METHOXSALEN**

**Caution** This drug is for ex vivo administration and must not to be injected directly into the patient.

**Note** Current Medicare Benefits Schedule item numbers for extracorporeal photopheresis for the treatment of chronic graft-versus host disease are: 13761 and 13762.

**Note** A new treatment episode is considered to have begun when treatment with this drug/extracorporeal photopheresis follows a relapse of the condition. There is no limit on the number of new treatment cycles that may be commenced, but re-treatment following a relapse must not commence under 'Continuing treatment'.

**Note** A maximum quantity (vials) of 12 with 1 repeat prescription provides 24 doses of this drug. An additional 25<sup>th</sup> dose can be prescribed under this treatment phase by issuance of a further prescription made out for one vial with nil repeats. Alternatively, the 25<sup>th</sup> dose can be sought under the 'Continuing treatment' restriction. The 26<sup>th</sup> dose and onwards must be requested under the 'Continuing treatment' restriction.

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

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

**Authority required (STREAMLINED)****12579**

Chronic graft versus host disease

Treatment Phase: Initial treatment in a treatment episode

**Clinical criteria:**

- The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; OR
- The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; OR
- The condition must have relapsed with each of the following conditions being met: (i) prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis last occurred at least 8 weeks ago, (ii) a subsequent trial of systemic corticosteroids at therapeutic doses has been completed.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug that is being administered within at least one of: (i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25<sup>th</sup> dose) of a treatment episode, **AND**
- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation, **AND**
- Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition.

**methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials**

12855N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	2555.95	Uvadex [TQ]

**▪ OTHER DERMATOLOGICAL PREPARATIONS****OTHER DERMATOLOGICAL PREPARATIONS***Agents for dermatitis, excluding corticosteroids***▪ OMALIZUMAB**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

- 1) a H2 receptor antagonist (150 mg twice per day); or
- 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
- 3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:
  - (i) demonstration of failure to achieve an adequate response to standard therapy; and
  - (ii) drug names and doses of standard therapies that the patient has failed; and
  - (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

### omalizumab 150 mg/mL injection, 1 mL syringe

11175E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*456.27	Xolair [NV]

### ■ OMALIZUMAB

**Note** A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

**Note** Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### Authority required

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

#### **Clinical criteria:**

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

### omalizumab 150 mg/mL injection, 1 mL syringe

11163M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*456.27	Xolair [NV]

## ■ SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### ■ PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

#### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

*Other anterior pituitary lobe hormones and analogues*

### ■ PEGVISOMANT

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

**Note** Special Pricing Arrangements apply.



**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au). Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs Programs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack**

11166Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*559.15	Somavert [PF]

▪ **PEGVISOMANT**

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

HSD (Private)

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR

2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

- two completed authority prescription forms ; and
- a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- a recent result of the IGF-1 level and the date of assessment ; and
- demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Acromegaly

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose. Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **pegvisomant 10 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack**

11167R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4018.31	Somavert [PF]

### **pegvisomant 15 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack**

11172B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4018.31	Somavert [PF]

### **pegvisomant 20 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack**

11174D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4018.31	Somavert [PF]

## HYPOTHALAMIC HORMONES

### *Somatostatin and analogues*

▪ LANREOTIDE

**Note** Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Authority required (STREAMLINED)**

**9261**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required (STREAMLINED)**

**9260**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe**

6425E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2630.19	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

**lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe**

6423C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1748.13	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

**lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe**

6424D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2310.41	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

▪ LANREOTIDE

**Note** Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

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

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

**Authority required (STREAMLINED)**

**10077**

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

**Clinical criteria:**

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must be aged 18 years or older.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

**lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe**

11527Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2630.19	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

▪ **OCTREOTIDE**

**Authority required (STREAMLINED)**

**9262**

Acromegaly

**Clinical criteria:**

- The condition must be controlled with octreotide immediate release injections, **AND**
  - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
  - The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
  - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
- In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**

**9313**

Functional carcinoid tumour

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**9288**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10566D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*829.39	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

**octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10549F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1099.29	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

**octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10558Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1255.99	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

▪ **OCTREOTIDE**

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

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

**Authority required (STREAMLINED)**

**10077**

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

**Clinical criteria:**

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must be aged 18 years or older.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

**octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

11894B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1255.99	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

▪ **OCTREOTIDE**

**Note** Pharmaceutical benefits that have the form octreotide 100 microgram/mL 5 x 1 mL ampoules can be substituted for octreotide 100 microgram/mL 5 x 1 mL vials in the case of a shortage.

**Authority required (STREAMLINED)**

**9233**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
  - Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
  - The treatment must be after failure of other therapy including dopamine agonists; OR
  - The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
  - The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
  - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
  - The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
  - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
- In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**

**9289**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**9232**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 100 microgram/mL injection, 5 x 1 mL ampoules**

6228T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*396.93	<sup>a</sup> Octreotide GH [HQ] <sup>a</sup> Sandostatin 0.1 [NV]	<sup>a</sup> Octreotide (SUN) [RA]

**octreotide 100 microgram/mL injection, 5 x 1 mL vials**

14177E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	11	..	*696.99	<sup>a</sup> Octreotide Acetate Omega (Canada) [GQ]

▪ **OCTREOTIDE**

**Note** Pharmaceutical benefits that have the form octreotide 500 microgram/mL 5 x 1 mL ampoules can be substituted for octreotide 500 microgram/mL 5 x 1 mL vials in the case of a shortage

**Authority required (STREAMLINED)**

**9233**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**

- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**

**9289**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**9232**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 500 microgram/mL injection, 5 x 1 mL ampoules**

6229W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*1919.01	<sup>a</sup> Octreotide GH [HQ] <sup>a</sup> Sandostatin 0.5 [NV]	<sup>a</sup> Octreotide (SUN) [RA]

**octreotide 500 microgram/mL injection, 5 x 1 mL vials**

14201K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	11	..	*1919.01	<sup>a</sup> Octreotide Acetate Omega (Canada) [GQ]

▪ **OCTREOTIDE**

**Note** Pharmaceutical benefits that have the form octreotide 50 microgram/mL 5 x 1 mL ampoules can be substituted for octreotide 50 microgram/mL 5 x 1 mL vials in the case of a shortage.

**Authority required (STREAMLINED)**

**9233**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**

**9289**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**

- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**9232**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 50 microgram/mL injection, 5 x 1 mL ampoules**

6227R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*203.07	<sup>a</sup> Octreotide GH [HQ] <sup>a</sup> Sandostatin 0.05 [NV]	<sup>a</sup> Octreotide (SUN) [RA]

**octreotide 50 microgram/mL injection, 5 x 1 mL vials**

14213C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	11	..	*691.05	<sup>a</sup> Octreotide Acetate Omega (Canada) [GQ]

▪ **PASIREOTIDE EMBONATE**

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 1 microgram per litre or 3 mIU/L; OR
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance. Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a) a completed authority prescription form; and
- b) a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; the date and result of GH or IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and
- d) a recent result of GH or IGF-1 levels must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**pasireotide (as embonate) 20 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10880P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7458.67	Signifor LAR [RJ]

**pasireotide (as embonate) 40 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10884W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7458.67	Signifor LAR [RJ]

**pasireotide (as embonate) 60 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10887B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7458.67	Signifor LAR [RJ]

**■ CALCIUM HOMEOSTASIS**  
**ANTI-PARATHYROID AGENTS**  
*Other anti-parathyroid agents*

**■ CINACALCET**

**Note** "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

**Authority required (STREAMLINED)**

**10063**

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a nephrologist.

**Clinical criteria:**

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.



**cinacalcet 30 mg tablet, 28**

11891W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*52.13	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**cinacalcet 60 mg tablet, 28**

11889R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*91.69	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**cinacalcet 90 mg tablet, 28**

11888Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*131.93	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

■ **CINACALCET**

**Note** "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

**Authority required**

Secondary hyperparathyroidism

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a nephrologist.

**Clinical criteria:**

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have failed to respond to conventional therapy, **AND**
- Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L; OR
- Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L.

During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved.

During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

**cinacalcet 30 mg tablet, 28**

9625N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*52.13	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**cinacalcet 60 mg tablet, 28**

9626P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*91.69	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**cinacalcet 90 mg tablet, 28**

9627Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*131.93	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

■ **ANTIINFECTIVES FOR SYSTEMIC USE**

■ **ANTIBACTERIALS FOR SYSTEMIC USE**

**MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS**

*Macrolides*

■ **AZITHROMYCIN**

**Authority required (STREAMLINED)**

**9604**

Mycobacterium avium complex infection

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**azithromycin 600 mg tablet, 8**

6221K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*123.87	Zithromax [PF]

NP

■ **ANTIMYCOBACTERIALS**

**DRUGS FOR TREATMENT OF TUBERCULOSIS**

*Antibiotics*

HSD (Private)

# ANTIINFECTIVES FOR SYSTEMIC USE

## ▪ RIFABUTIN

### Authority required (STREAMLINED)

**9560**

Mycobacterium avium complex infection

### Clinical criteria:

- Patient must be human immunodeficiency virus (HIV) positive.

### Authority required (STREAMLINED)

**9622**

Mycobacterium avium complex infection

### Clinical criteria:

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

### rifabutin 150 mg capsule, 30

6195C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	4	5	..	*555.55	Mycobutin [PF]

## ▪ ANTIVIRALS FOR SYSTEMIC USE

### DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

## ▪ GANCICLOVIR

### Authority required (STREAMLINED)

**15784**

Cytomegalovirus infection and disease

### Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

### Authority required (STREAMLINED)

**15782**

Cytomegalovirus infection and disease

### Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

### ganciclovir 500 mg injection, 5 vials

6136Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*250.13	<sup>a</sup> Cymevene [PB]	<sup>a</sup> GANCICLOVIR SXP [XC]

## ▪ VALACICLOVIR

### Authority required (STREAMLINED)

**9267**

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

### Clinical criteria:

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

### valaciclovir 500 mg tablet, 100

6280M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*216.67	<sup>a</sup> APX-Valaciclovir [TY] <sup>a</sup> Valaciclovir RBX [RA]	<sup>a</sup> Valaciclovir APOTEX [GX]
			<sup>B</sup> 14.05	*230.72	<sup>a</sup> Valtrex [RW]	

## ▪ VALGANCICLOVIR

### Authority required (STREAMLINED)

**15784**

Cytomegalovirus infection and disease

### Clinical criteria:

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

### Authority required (STREAMLINED)

**15782**

Cytomegalovirus infection and disease

### Clinical criteria:

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

**valganciclovir 50 mg/mL powder for oral liquid, 100 mL**

9675F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	11	5	..	*#4397.97	Valcyte [PB]

**valganciclovir 450 mg tablet, 60**

6357N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*503.93	<sup>a</sup> Valganciclovir Sandoz [SZ]	<sup>a</sup> Valganciclovir Viatrix [AL]

*Antivirals for treatment of HCV infections*

▪ **GLECAPREVIR + PIBRENTASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 16 weeks.
- The application must include details of the prior treatment regimen containing an NS5A inhibitor.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11337Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	16895.34	Maviret [VE]

NP

▪ **GLECAPREVIR + PIBRENTASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11346E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	16895.34	Maviret [VE]

NP

▪ **GLECAPREVIR + PIBRENTASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11355P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	16895.34	Maviret [VE]

NP

▪ **SOFOSBUVIR + VELPATASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

### sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

11144M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	11923.67	Epclusa [GI]

### ▪ SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR

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

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

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic hepatitis C infection

#### Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
  - Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
  - The treatment must be limited to a maximum duration of 12 weeks.
- The application must include details of the prior treatment regimen containing an NS5A inhibitor.

### sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28

11659P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	11923.67	Vosevi [GI]

## ▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### ▪ ANTINEOPLASTIC AGENTS

#### ANTIMETABOLITES

##### *Pyrimidine analogues*

### ▪ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Acute Myeloid Leukaemia

#### Clinical criteria:

- The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).

### azacitidine 100 mg injection, 1 vial

12784W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*382.75	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

### ▪ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must not have progressive disease.
- Up to 6 cycles will be authorised.

### azacitidine 100 mg injection, 1 vial

13033Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*382.75	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO]

<sup>a</sup> Azacitidine MSN [JU]

<sup>a</sup> Azacitidine Sandoz [SZ]

<sup>a</sup> Azacitidine-Teva [TB]

■ **AZACITIDINE**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

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

- (a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
- (b) full blood examination report.

**azacitidine 100 mg injection, 1 vial**

13038F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*382.75	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

■ **AZACITIDINE**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS). Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:
  - a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
  - b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
  - c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
  - d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
  - e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
  - f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

- a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

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

- (a) The patient's International Prognostic Scoring System (IPSS) score

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

- (a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- (b) full blood examination report; and

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

(c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

### azacitidine 100 mg injection, 1 vial

13039G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*382.75	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

### ■ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required (STREAMLINED)**

**13012**

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

### azacitidine 100 mg injection, 1 vial

13040H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*382.75	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

### ■ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report, **AND**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and
- (b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

- (a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and
- (b) full blood examination report

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

**azacitidine 100 mg injection, 1 vial**

6100C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*382.75	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

▪ **AZACITIDINE**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic Myelomonocytic Leukaemia  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.  
Up to 6 cycles will be authorised.

**azacitidine 100 mg injection, 1 vial**

6138C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*382.75	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

HSD (Private)

**CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES**

*Anthracyclines and related substances*

▪ **DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)**

**Authority required (STREAMLINED)**

**9287**

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

**Authority required (STREAMLINED)**

**9223**

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

**doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial**

6249X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*584.51	<sup>a</sup> Caelyx [BX]	<sup>a</sup> Liposomal Doxorubicin SUN [RA]

**PROTEIN KINASE INHIBITORS**

*Janus-associated kinase (JAK) inhibitors*

▪ **RUXOLITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**13876**

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.

**Treatment criteria:**

- Must be treated by a haematologist; OR

- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**ruxolitinib 10 mg tablet, 56**

13231J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4798.67	Jakavi [NV]

**ruxolitinib 5 mg tablet, 56**

13244C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2423.67	Jakavi [NV]

▪ **RUXOLITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**13911**

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).

Steroid-refractory disease is defined as:

(a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or

(b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.

Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:

(a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or

(b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

(a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

(b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.



This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**ruxolitinib 10 mg tablet, 56**

13236P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4798.67	Jakavi [NV]

**ruxolitinib 5 mg tablet, 56**

13239T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2423.67	Jakavi [NV]

*Other protein kinase inhibitors*

▪ **MIDOSTAURIN**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Induction / Consolidation therapy

**Clinical criteria:**

- Patient must not have received prior chemotherapy as induction therapy for this condition; OR
- The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy and the patient must not have progressive disease, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.

A maximum of 6 cycles will be authorised under this restriction in a lifetime.

Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**midostaurin 25 mg capsule, 56**

11506N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	9260.04	Rydapt [NV]

▪ **MIDOSTAURIN**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.

A maximum of 9 cycles will be authorised under this restriction in a lifetime.  
 Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.  
 If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.  
 Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**midostaurin 25 mg capsule, 112**

11518F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18471.41	Rydapt [NV]

▪ **MIDOSTAURIN**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Acute Myeloid Leukaemia  
 Treatment Phase: Maintenance therapy - Initial treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin confirmed through a bone marrow biopsy pathology report, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority.

A maximum of 3 cycles will be authorised under this restriction in a lifetime.  
 Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.  
 If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.  
 Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and
- confirmation that the patient does not have progressive disease; and
- details (date, unique identifying number/code or provider number) of a recent bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient is in complete remission; and
- details (date, unique identifying number/code or provider number) of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**midostaurin 25 mg capsule, 112**

11531X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18471.41	Rydapt [NV]

**MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES**

*CD20 (Clusters of Differentiation 20) inhibitors*

▪ **RITUXIMAB**

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

**rituximab 500 mg/50 mL injection, 50 mL vial**

13095F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*458.33	<sup>a</sup> Riximyo [SZ] <sup>a</sup> Truxima [EW]	<sup>a</sup> Ruxience [PF]

▪ **RITUXIMAB**

**Note** Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

**rituximab 100 mg/10 mL injection, 2 x 10 mL vials**

13096G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*278.49	<sup>a</sup> Riximyo [SZ]	<sup>a</sup> Truxima [EW]

**rituximab 100 mg/10 mL injection, 10 mL vial**

13109Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	..	..	*278.49	<sup>a</sup> Ruxience [PF]

**OTHER ANTINEOPLASTIC AGENTS**

*Other antineoplastic agents*

▪ **SELINEXOR**

**Caution** This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**selinexor 20 mg tablet, 16**

13099K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	9408.67	Xpovio [TG]

▪ **SELINEXOR**

**Caution** This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 100 mg per week

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 100 mg per week

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**selinexor 20 mg tablet, 20**

13103P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	11748.67	Xpovio [TG]

▪ **SELINEXOR**

**Caution** This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPoS](http://www.servicesaustralia.gov.au/HPoS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 160 mg per week

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 160 mg per week

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
  - Patient must not have developed disease progression while receiving treatment with this drug for this condition.
- Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**selinexor 20 mg tablet, 32**

13105R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18768.67	Xpovio [TG]

**IMMUNOSTIMULANTS**  
**IMMUNOSTIMULANTS**  
*Colony stimulating factors*

**FILGRASTIM**

**Authority required (STREAMLINED)**

**8674**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**8667**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**8672**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

**8668**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

**8671**

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required (STREAMLINED)**

**8696**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required (STREAMLINED)**

**8669**

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required (STREAMLINED)**

**8670**

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required (STREAMLINED)**

**8673**

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes**

5830W	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2		11	..	*266.25	Nivestim [PF]

▪ **FILGRASTIM**

**Note** Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**8674**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**8667**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**8672**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

**8668**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

**8671**

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required (STREAMLINED)**

**8696**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required (STREAMLINED)**

**8669**

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required (STREAMLINED)**

**8670**

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required (STREAMLINED)**

**8673**

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

6292E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*400.33	<sup>a</sup> Nivestim [PF]

**filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

2733W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*400.35	<sup>a</sup> Zarzio [SZ]

▪ **FILGRASTIM**

**Note** Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**8674**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**8667**



Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**8672**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

**8668**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

**8671**

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required (STREAMLINED)**

**8696**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required (STREAMLINED)**

**8669**

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required (STREAMLINED)**

**8670**

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required (STREAMLINED)**

**8673**

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

6291D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*252.99	<sup>a</sup> Nivestim [PF]

**filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

2747N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*252.99	<sup>a</sup> Zarzio [SZ]

▪ **LIPEGFILGRASTIM**

**Authority required (STREAMLINED)**

**9224**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**

HSD (Private)

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

### **Authority required (STREAMLINED)**

**9322**

Chemotherapy-induced neutropenia

#### **Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

### **lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

10931H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	1164.92	Lonquex [TB]

## ▪ PEGFILGRASTIM

### **Authority required (STREAMLINED)**

**9235**

Chemotherapy-induced neutropenia

#### **Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

### **Authority required (STREAMLINED)**

**9303**

Chemotherapy-induced neutropenia

#### **Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

### **pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

6363X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	104.30	<sup>a</sup> Pelgraz [OC]	<sup>a</sup> Ziextenzo [SZ]

## *Interferons*

## ▪ INTERFERON GAMMA-1B

### **Authority required (STREAMLINED)**

**9639**

Chronic granulomatous disease

#### **Clinical criteria:**

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

### **interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials**

6148N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1768.23	Imukin [LM]

## ▪ PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- a nurse educator/counsellor for patients; and
- 24-hour access by patients to medical advice; and
- an established liver clinic.

### **Authority required (STREAMLINED)**

**9603**

Chronic hepatitis C infection

#### **Treatment criteria:**

- Must be treated in an accredited treatment centre.

#### **Population criteria:**

- Patient must be aged 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

#### **Clinical criteria:**

- Patient must have compensated liver disease, **AND**

- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.

Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6439X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	2	5	..	*993.57	Pegasys [XO]

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

6449K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	2	5	..	*1145.39	Pegasys [XO]

*Other immunostimulants*

■ **PLERIXAFOR**

**Note** Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

**Authority required (STREAMLINED)**

**9329**

Mobilisation of haematopoietic stem cells

**Clinical criteria:**

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; OR
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**
- Patient must have failed previous stem cell collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**plerixafor 24 mg/1.2 mL injection, 1.2 mL vial**

10084R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	4065.51	<sup>a</sup> Mozobil [GZ] <sup>a</sup> PLERIXAFOR EUGIA [YG]	<sup>a</sup> Plerixafor ARX [XT]

■ **IMMUNOSUPPRESSANTS**

**IMMUNOSUPPRESSANTS**

*Selective immunosuppressants*

■ **ABATACEPT**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1

application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required (STREAMLINED)**

**14555**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

**abatacept 250 mg injection, 1 vial**

13705H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*827.37	Orencia [BQ]

▪ **ABATACEPT**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab

course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for commencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001



**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**abatacept 250 mg injection, 1 vial**

9621J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	281.57	Orencia [BQ]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**9689**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**9690**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy )

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 250 mg capsule, 100**

6208R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*167.67	<sup>a</sup> APO-Mycophenolate [TX] <sup>a</sup> Pharmacor Mycophenolate 250 [CR]	<sup>a</sup> Mycophenolate Sandoz [SZ]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**9691**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**9693**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

6364Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*#520.41	<sup>a</sup> CellCept [RO]	<sup>a</sup> Pharmacor Mycophenolate [CR]

**mycophenolate mofetil 500 mg tablet, 50**

6209T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*167.55	<sup>a</sup> ARX-MYCOPHENOLATE [XT] <sup>a</sup> MycoCept [RF] <sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> Ceptolate [AF] <sup>a</sup> Mycophenolate GH [GQ] <sup>a</sup> Pharmacor Mycophenolate 500 [CR]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Note** Management includes initiation, stabilisation and review of therapy as required.

**Authority required (STREAMLINED)**

**9692**

Prophylaxis of renal allograft rejection

Treatment Phase: Management

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**9809**

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

**Clinical criteria:**

- The condition must be proven by biopsy.

**Treatment criteria:**

- Must be treated by a nephrologist or in consultation with a nephrologist.  
The name of the consulting nephrologist must be included in the patient medical records.

**mycophenolate 180 mg enteric tablet, 120**

6369F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*187.11	<sup>a</sup> Mycophenolic Acid ARX [XT]	<sup>a</sup> Myfortic [NV]

**mycophenolate 360 mg enteric tablet, 120**

6370G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*365.51	<sup>a</sup> Mycophenolic Acid ARX [XT] <sup>a</sup> Myfortic [NV]	<sup>a</sup> MYCOTEX [CR]

*Tumor necrosis factor alpha (TNF-alpha) inhibitors*

▪ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Authority required (STREAMLINED)**

**14107**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13229G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	470.61	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12368Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	534.86	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

### Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Authority required (STREAMLINED)**

**14107**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13210G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	470.61	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12384T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	534.86	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

▪ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological

medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

## **Authority required (STREAMLINED)**

### **14107**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or



(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14285W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	576.18	<sup>a</sup> Abrilada [PF]

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

13292N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	598.79	<sup>a</sup> Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12349Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*576.17	<sup>a</sup> Amgevita [XT]

▪ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12335F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	470.61	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9680L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	534.86	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

▪ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication

HSD (Private)

specificities: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and  
(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12396K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	470.61	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9679K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	534.86	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]	

▪ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.



(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records. The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14276J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	576.18	<sup>a</sup> Abrilada [PF]

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12443X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	598.79	<sup>a</sup> Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12439Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*576.17	<sup>a</sup> Amgevita [XT]

▪ **ETANERCEPT**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules.

However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

## **Authority required (STREAMLINED)**

**14155**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

13295R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*782.03	Enbrel [PF]

▪ **ETANERCEPT**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

## (1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

## (2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

## (3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

## (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

## (5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

## (6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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

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

**Authority required (STREAMLINED)****14155**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

13326J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	782.01	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

13332Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	782.01	<sup>a</sup> Enbrel [PF]

▪ **ETANERCEPT**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline

measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

## **Authority required**

Severe active juvenile idiopathic arthritis



Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack**

6367D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	395.35	Enbrel [PF]

▪ **ETANERCEPT**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

## (2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

## (3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

## (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

## (5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

## (6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

## **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

## **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

9641K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	782.01	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

9615C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	782.01	<sup>a</sup> Enbrel [PF]

**▪ INFLIXIMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Crohn Disease Activity Index (CDAI) Score; or
  - (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
  - (iii) the date of the most recent clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**infliximab 100 mg injection, 1 vial**

11399Y	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-

subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:



(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

**infliximab 100 mg injection, 1 vial**

11412P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease

may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**infliximab 100 mg injection, 1 vial**

11445J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

## ■ INFLIXIMAB

### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11489Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required (STREAMLINED)**

**9632**

Acute severe ulcerative colitis

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

**Clinical criteria:**

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**infliximab 100 mg injection, 1 vial**

10057H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	1	..	*976.72	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more

immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required (STREAMLINED)**

**12051**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11396T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*976.72	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

■ **INFLIXIMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an

alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreatment of conventional therapies is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required (STREAMLINED)**

**9775**

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The PCDAI assessment must be no more than 1 month old at the time of prescribing.

The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

**infliximab 100 mg injection, 1 vial**

11450P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*976.72	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess



response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) **Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11498E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

HSD (Private)

## (1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years). Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

## (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

## (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

## (4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**infliximab 100 mg injection, 1 vial**

11797X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required (STREAMLINED)**

**9732**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

**infliximab 100 mg injection, 1 vial**

11432Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*976.72	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

**■ INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required (STREAMLINED)**

**14689**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- an ESR measurement no greater than 25 mm per hour; or
- a CRP measurement no greater than 10 mg per L; or
- an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required (STREAMLINED)**

**14723**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11488P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	3	..	*976.72	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

## (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

## (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

## (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

## (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

## (5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required (STREAMLINED)****9472**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:



an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11515C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*976.72	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11590B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

■ **INFLIXIMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the

full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required (STREAMLINED)**

##### **14505**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

**infliximab 100 mg injection, 1 vial**

11483J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*589.50	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

■ **INFLIXIMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a

written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required (STREAMLINED)**

##### **14585**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

**infliximab 100 mg injection, 1 vial**

13700C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*589.50	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

■ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be

HSD (Private)



deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions. For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

#### **Authority required (STREAMLINED)**

##### **9602**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required (STREAMLINED)**

##### **9584**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11595G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*976.72	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

**(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required (STREAMLINED)**

**12074**

Moderate to severe ulcerative colitis  
Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**infliximab 100 mg injection, 1 vial**

11796W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*976.72	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the active joint count, ESR and/or CRP result and date of results;

(b) details of prior treatment, including dose and date/duration of treatment.

(c) If applicable, details of any contraindications/intolerances.

(d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the active joint count, ESR and/or CRP result and date of result;
- (b) the most recent biological agent and the date of the last continuing prescription.
- (c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**infliximab 100 mg injection, 1 vial**

13724H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:



Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

#### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and
- (iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

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**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below. To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks

from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**infliximab 100 mg injection, 1 vial**

13778E	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

■ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

HSD (Private)

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).

Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

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**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR

- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

An adult patient who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A patient, aged 6 to 17 years, who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a PUCAI score of less than 10 will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR

- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

**Population criteria:**

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Details of the accepted toxicities including severity can be found on the Services Australia website.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR



- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

10184B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine,

'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
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HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

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## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**infliximab 100 mg injection, 1 vial**

6397Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years );

or

- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreatment of conventional therapies is not required.

## **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

### **Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR
- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.

The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).



**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

- the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and
- details of prior biological medicine treatment including details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
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Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or commencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include a PCDAI assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

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**infliximab 100 mg injection, 1 vial**

9612X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that

contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

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## **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Population criteria:**

- Patient must be at least 18 years of age.

### **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**

- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

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 Or mailed to:  
 Services Australia  
 Complex Drugs

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**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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Or mailed to:

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Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

**AND**

- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- faeces: higher than normal lactoferrin or calprotectin level; or
- diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
- (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
- (iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs



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**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

9613Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a

minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

## **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment (new patient or Commencement of treatment after more than 5 years break in therapy - Initial 1)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
- (ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note** It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include an assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks of treatment with this drug will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 or Initial 2 treatment) or 2 repeats (first Continuing or Subsequent Continuing treatment).

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

9674E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

#### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by

- a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- a baseline BASDAI score; and
- a completed Exercise Program Self Certification Form included in the supporting information form; and
- baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**

- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:



- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
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 HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**infliximab 100 mg injection, 1 vial**

6448J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Remicade [JC]

HSD (Private)

## ■ INFLIXIMAB

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent

continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) **Recommencement of treatment after a 5-year break in PBS-subsidised therapy.**

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

6496X	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1		..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus

HSD (Private)

psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**



- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- (b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- (c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - (ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

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Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- (ii) details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy**

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HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy**

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**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**

• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

9617E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	202.28	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

*Interleukin inhibitors*

▪ **ANAKINRA**

**Note** This drug is not PBS-subsidised for conditions other than CAPS.

**Authority required (STREAMLINED)**

**5450**

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

**Treatment criteria:**

- Must be treated by a rheumatologist or in consultation with a rheumatologist; OR



- Must be treated by a clinical immunologist or in consultation with a clinical immunologist. A diagnosis of CAPS must be documented in the patient's medical records.

**anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes**

10263E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1195.31	Kineret [ZO]

▪ **SILTUXIMAB**

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of iMCD consistent with the latest international, evidence-based consensus diagnostic criteria for this condition with the relevant diagnostic findings documented in the patient's medical records, **AND**
- The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD: (i) human herpes virus-8 infection, (ii) an Epstein-Barr virus-lymphoproliferative disorder, (iii) an acute/uncontrolled infection (e.g. cytomegalovirus, toxoplasmosis, human immunodeficiency virus, tuberculosis) leading to inflammation with adenopathy, (iv) an autoimmune/autoinflammatory disease, (v) a malignant/lymphoproliferative disorder.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist, **AND**
- Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed; OR
- Patient must be undergoing treatment through this treatment phase for up to the first 5 doses in a lifetime, where the full number of repeats was not prescribed with the first prescription.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

**Note** The international, evidence-based consensus iMCD diagnostic criteria developed by an international working group of clinical experts lists various findings under 'Major' and 'Minor' diagnostic criteria that constitute a diagnosis of iMCD. At the time of writing, under these consensus criteria, diagnostic findings that meet: (i) both Major criteria and (ii) at least 2 of 11 Minor criteria including at least 1 laboratory abnormality and (iii) exclude various differential diagnoses, form a diagnosis of iMCD.

Details of these criteria are presented in Table 2 of the following literature article:

Fajgenbaum DC, Uldrick TS, Bagg A, Frank D et. al. International, evidence-based consensus diagnostic criteria for HHV-8-negative/idiopathic multicentric Castleman disease. **Blood** 2017; 129(12): 1646-1657.

Where updates to these diagnostic criteria have occurred since the publication, refer to the latest version.

Do not contact the PBS-administrator to discuss whether an individual patient meets these consensus criteria.

**Authority required**

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

**siltuximab 100 mg injection, 1 vial**

12930M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	4	..	*1607.23	Sylvant [RJ]

**siltuximab 400 mg injection, 1 vial**

12934R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	4	..	*6282.87	Sylvant [RJ]

▪ **TOCILIZUMAB**

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

12766X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.55	Actemra [RO]

HSD (Private)

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

12805Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	430.28	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

12787B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.86	Actemra [RO]

▪ **TOCILIZUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should

be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Authority required (STREAMLINED)**

**14082**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

13312P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	220.55	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

13338B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	430.28	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

13311N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*179.63	Actemra [RO]

▪ **TOCILIZUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive

multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

#### **Authority required (STREAMLINED)**

**14179**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
  - Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.
- An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response

assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

13329M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*432.43	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

13323F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*851.89	Actemra [RO]

▪ **TOCILIZUMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application

following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

#### **Authority required (STREAMLINED)**

**14485**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

### tocilizumab 200 mg/10 mL injection, 10 mL vial

13716X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	220.55	Actemra [RO]

### tocilizumab 400 mg/20 mL injection, 20 mL vial

13731Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	430.28	Actemra [RO]

### tocilizumab 80 mg/4 mL injection, 4 mL vial

13696W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*179.63	Actemra [RO]

## ■ TOCILIZUMAB

### Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

### **Authority required (STREAMLINED)**

**14179**

Systemic juvenile idiopathic arthritis



Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

13315T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*350.59	Actemra [RO]

▪ **TOCILIZUMAB**

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment.

Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment.

Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

12795K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.55	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

12810F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	430.28	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

12811G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.86	Actemra [RO]

▪ **TOCILIZUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

## **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

## **Population criteria:**

- Patient must be under 18 years of age.

## **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and
- (b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

1423X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.55	Actemra [RO]

HSD (Private)

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

1464C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	430.28	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

1419Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.86	Actemra [RO]

▪ **TOCILIZUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should

be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**



- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response

assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

10079L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.55	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

10060L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	430.28	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

10068X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.86	Actemra [RO]

■ **TOCILIZUMAB**

**Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.

**(1) Initial treatment.**

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy.

A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

**(4) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

**(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.**

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i)

hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

(1) completed authority prescription form(s); and

(2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

(a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;

(b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;

(c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Active joints are defined as:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- completed authority prescription form(s); and
- a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis  
Treatment Phase: Continuing Treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

10071C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.55	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

10078K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	430.28	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

10073E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.86	Actemra [RO]

■ **TOCILIZUMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

HSD (Private)



The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

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HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

9672C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	220.55	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

9673D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	430.28	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

9671B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	94.86	Actemra [RO]

■ **USTEKINUMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- two completed authority prescription forms; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- patient must have evidence of intestinal inflammation;
- patient must be assessed clinically as being in a high faecal output state;
- patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- faeces: higher than normal lactoferrin or calprotectin level; or
- diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.



Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

#### **AND**

- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**ustekinumab 130 mg/26 mL injection, 26 mL vial**

11164N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*12048.67	Stelara [JC]

**■ USTEKINUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

HSD (Private)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and  
 (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:  
 (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and  
 (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and  
 (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:  
 (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and  
 (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4

vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**ustekinumab 130 mg/26 mL injection, 26 mL vial**

13255P	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*12048.67	Stelara [JC]

▪ **USTEKINUMAB**

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same

treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction. A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Re commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

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

**Note** Special Pricing Arrangements apply.

## **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
  - (ii) details of prior biological medicine treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ustekinumab 130 mg/26 mL injection, 26 mL vial**

13804M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*12048.67	Stelara [JC]

*Calcineurin inhibitors*

▪ **CICLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**9831**

Management of transplant rejection

**Clinical criteria:**

- The treatment must be used by organ or tissue transplant recipients.

**ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules**

6109M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	66.77	Sandimmun [NV]

▪ **CICLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**9764**

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**9695**

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

**Authority required (STREAMLINED)**

**15361**

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.

For patients who do not demonstrate an adequate response to ciclosporin, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

**9694**

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

**Treatment criteria:**

- Must be treated by a nephrologist.

**Authority required (STREAMLINED)**

**9742**

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

**Treatment criteria:**



- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

**ciclosporin 100 mg/mL oral liquid, 50 mL**

6125J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	4	5	..	*1311.83	Neoral [NV]	

**ciclosporin 25 mg capsule, 30**

6352H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*100.83	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 25 [NV]

**ciclosporin 50 mg capsule, 30**

6353J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*199.47	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 50 [NV]

**ciclosporin 10 mg capsule, 60**

6232B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	2	5	..	*87.07	Neoral 10 [NV]	

**ciclosporin 100 mg capsule, 30**

6354K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*397.43	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 100 [NV]

▪ **TACROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**9697**

Management of rejection in patients following organ or tissue transplantation

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

**tacrolimus 500 microgram capsule, 100**

6328C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*115.75	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 0.5 [CR] <sup>a</sup> Tacrograf [RW]

**tacrolimus 500 microgram modified release capsule, 30**

9681M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*87.71	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 1 mg capsule, 100**

6216E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*222.83	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 1 [CR] <sup>a</sup> Tacrograf [RW]

**tacrolimus 3 mg modified release capsule, 50**

11920J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*693.19	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 1 mg modified release capsule, 60**

9682N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*137.17	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 5 mg capsule, 50**

6217F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*543.81	<sup>a</sup> Pharmacor Tacrolimus 5 [CR] <sup>a</sup> Tacrograf [RW]	<sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]

**tacrolimus 5 mg modified release capsule, 30**

9683P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*789.13	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 750 microgram capsule, 100**

10875J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	2	5	..	*212.67	Tacrolimus Sandoz [SZ]	

HSD (Private)

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### tacrolimus 2 mg capsule, 100

10879N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*496.75	Tacrolimus Sandoz [SZ]

### Monoclonal antibodies

#### ■ ALEMTUZUMAB

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

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

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

#### Authority required (STREAMLINED)

**9589**

Multiple sclerosis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

#### **Treatment criteria:**

- Must be treated by a neurologist.

### alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10246G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	..	..	*30897.93	Lemtrada [GZ]

#### ■ ALEMTUZUMAB

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

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

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

#### Authority required (STREAMLINED)

**9636**

Multiple sclerosis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

#### **Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

### alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10243D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	..	..	*51464.12	Lemtrada [GZ]

#### ■ ANIFROLUMAB

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

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

**Note** Special Pricing Arrangements apply.

**Note** SLEDAI-2K can be accessed via Gladman 2002 J. Rheumatol. 29 (2) 288-291 or from AstraZeneca Medical Information on 1800 805 342.

#### Authority required

Systemic lupus erythematosus

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have a confirmed and documented diagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019, **AND**
- Patient must have persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points, **AND**
- Patient must be currently receiving hydroxychloroquine, with treatment received for at least 12 weeks, unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must be currently receiving immunosuppressant medication, with treatment received for at least 12 weeks, with either: (i) minimum dose of methotrexate 20 mg per week, (ii) azathioprine 100 mg per day, (iii) mycophenolate 1,000 mg per day unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must be currently receiving prednisolone or equivalent of at least 7.5 mg per day, with treatment received for at least 4 weeks, unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must not have either: (i) severe active lupus nephritis, (ii) severe active central nervous system systemic lupus erythematosus.

**Treatment criteria:**

- Must be treated by a specialist physician experienced in the management of this condition.
- If prednisolone or equivalent is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated of at least 7.5 mg per day, the patient must have received at least 12 weeks of continuous treatment with each of at least 2 of the following: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day. Where two of: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; or (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to prednisolone or equivalent: at least one of the remaining tolerated therapies must be trialled at a minimum dose as mentioned above.
- If the patient has a contraindication/severe intolerance to each of: (i) prednisolone or equivalent of at least 7.5 mg per day; (ii) hydroxychloroquine; (iii) methotrexate at a dose of at least 20 mg per week; (iv) azathioprine at a dose of at least 100 mg per day; (v) mycophenolate at a dose of at least 1,000 mg per day; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application.

The authority application must be made in writing via HPOS form upload or mail and must include:

- (a) details of the ACR/EULAR SLE Classification Criteria 2019 confirming diagnosis of SLE;
- (b) details (date and score) of the completed SLEDAI-2K score sheet;
- (c) details of current systemic therapy used (dosage, date of commencement and duration of therapy including prior anifrolumab use);
- (d) details of contraindication/intolerances to prior therapies (drug name, the degree of toxicity and dose).

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Systemic lupus erythematosus

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 July 2024, **AND**
- Patient must have had a confirmed and documented diagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019 prior to commencing therapy with this drug for this condition, **AND**
- Patient must have had persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points prior to commencing therapy with this drug for this condition, **AND**
- Patient must have been receiving hydroxychloroquine for at least 12 weeks prior to commencing therapy with this drug for this condition, **AND**
- Patient must have been receiving immunosuppressant medication for at least 12 weeks with either (i) minimum dose of methotrexate 20 mg per week (ii) azathioprine 100 mg per day (iii) mycophenolate 1,000 mg per day, prior to commencing therapy with this drug for this condition unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must have been receiving prednisolone or equivalent of at least 7.5 mg per day for at least 4 weeks prior to commencing therapy with this drug for this condition unless contraindicated/intolerant necessitating treatment withdrawal, **AND**

**AND**

- Patient must not have either: (i) severe active lupus nephritis, (ii) severe active central nervous system systemic lupus erythematosus.

**Treatment criteria:**

- Must be treated by a specialist physician experienced in the management of this condition.

If prednisolone or equivalent is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at least 7.5 mg per day, the patient must have received at least 12 weeks of continuous treatment with each of at least 2 of the following: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day.

Where two of: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; or (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to prednisolone or equivalent: at least one of the remaining tolerated therapies must be trialled at a minimum dose as mentioned above.

If the patient has a contraindication/severe intolerance to each of: (i) prednisolone or equivalent of at least 7.5 mg per day; (ii) hydroxychloroquine; (iii) methotrexate at a dose of at least 20 mg per week; (iv) azathioprine at a dose of at least 100 mg per day; (v) mycophenolate at a dose of at least 1,000 mg per day; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application.

The authority application must be made in writing via HPOS form upload or mail and must include:

- (a) details of the ACR/EULAR SLE Classification Criteria 2019 confirming diagnosis of SLE;
  - (b) details (date and score) of the completed SLEDAI-2K score sheet;
  - (c) details of current systemic therapy used (dosage, date of commencement and duration of therapy including prior anifrolumab use);
  - (d) details of contraindication/intolerances to prior therapies (drug name, the degree of toxicity and dose).
- All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Systemic lupus erythematosus

Treatment Phase: Continuing or recommencement of treatment (within 12 months of a treatment break)

**Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must be responding to treatment if they have received less than 12 months of treatment with this drug for this condition; OR
- Patient must have attained a Lupus Low Disease Activity State (LLDAS) and maintained this state while on treatment.

**Treatment criteria:**

- Must be treated by a specialist physician experienced in the management of this condition.

Lupus Low Disease Activity State (LLDAS) is defined as:

- (a) Total SLEDAI-2K of not greater than 4, with no major activity in major organ systems (renal, central nervous system (CNS), cardiopulmonary, vasculitis, fever); and
- (b) No new features of lupus disease activity compared with the previous assessment, and
- (c) Physician Global Assessment (PGA) of not greater than 1, and
- (d) Current prednisolone (or equivalent) dose of not greater than 7.5 mg daily, and
- (e) Well tolerated standard maintenance doses of anti-malarial and immunosuppressive drugs are allowed.

Where retreatment with anifrolumab after a break in PBS-subsidised treatment with anifrolumab is being sought, the date of cessation of the previous treatment course with anifrolumab must be included in the application. Recommencement of treatment with anifrolumab for severe SLE is within 12 months from the date that treatment was ceased.

**Note** PGA can be accessed via Petri 2005 N Engl J Med 353: 2550-8.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**anifrolumab 300 mg/2 mL injection, 2 mL vial**

14189T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1496.67	Saphnelo [AP]

▪ **NATALIZUMAB**

**Caution** Progressive multifocal leukoencephalopathy has been reported with this drug.

**Authority required (STREAMLINED)**

**13625**

Clinically definite relapsing-remitting multiple sclerosis

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

**natalizumab 300 mg/15 mL injection, 15 mL vial**

9624M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	983.46	Tysabri [BD]

**natalizumab 150 mg/mL injection, 2 x 1 mL syringes**

13820J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	983.46	Tysabri [BD]

▪ **OCRELIZUMAB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**9523**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

**9635**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a neurologist.

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

## ocrelizumab 300 mg/10 mL injection, 10 mL vial

11237K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*16705.03	Ocrevus [RO]

### ▪ VEDOLIZUMAB

#### Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Special Pricing Arrangements apply.

**Note** Patient must be assessed as having an inadequate response to the drug after completing an initial infusion regimen at 0, 2, and 6 weeks and prior to 10 weeks.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 4 (additional dose at week 10)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in this treatment cycle, **AND**
- Patient must have received 3 doses of initial treatment under either (i) initial 1, (ii) initial 2, (iii) initial 3, **AND**
- Patient must not have achieved an adequate response to this drug after a total of 3 doses of initial treatment under either (i) initial 1, (ii) initial 2, (iii) initial 3 under this restriction, **AND**
- The treatment must not exceed a total of 4 doses to be administered at weeks 0, 2, 6 and 10 under the initial treatment phase.

**Population criteria:**

- Patient must be at least 18 years of age.

A maximum quantity and number of repeats to provide for an additional dose of this drug consisting of one vial of 300 mg, with one dose to be administered at week 10, will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted prior to 10 weeks and a second assessment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

An adequate response to this drug defined as:

a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or

(a) an improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or

(ii) faeces: normalisation of lactoferrin or calprotectin level; or

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**vedolizumab 300 mg injection, 1 vial**

14614E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2998.60	Entyvio [TK]

▪ **VEDOLIZUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Special Pricing Arrangements apply.

## **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

## **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

## **Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

## **Population criteria:**

- Patient must be at least 18 years of age.

Application for authorisation of initial treatment must be in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Moderate to severe ulcerative colitis



Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be at least 18 years of age.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**vedolizumab 300 mg injection, 1 vial**

10398G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2998.60	Entyvio [TK]

▪ **VEDOLIZUMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- the patient has never been prescribed the newly listed biological medicine; and
- the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Special Pricing Arrangements apply.

## **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

### **Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

### **AND**

- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
- (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
- (iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

- (a) details of the proposed prescription; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
- (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
- (iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**vedolizumab 300 mg injection, 1 vial**

10415E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2998.60	Entyvio [TK]

▪ **VEDOLIZUMAB**

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

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

**Note** Special Pricing Arrangements apply.



**Authority required**

Moderate to severe chronic pouchitis

Treatment Phase: Initial 1 treatment (new patient)

**Clinical criteria:**

- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis (UC) at least one year previously, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5, **AND**
- Patient must have a minimum endoscopic mPDAI sub-score of at least 2, **AND**
- Patient must have had at least 3 recurrent episodes of pouchitis within the previous year each of which was treated with at least: (i) 2 weeks of antibiotic, (ii) other prescription therapy; OR
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- The treatment must be initiated in combination with standard of care antibiotic.
- The assessment of a patient's response to this initial course of treatment must be made after the third dose of vedolizumab so there is an adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14. Where a response assessment is not conducted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

Application for authorisation of initial treatment must be in writing and must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and endoscopic mPDAI subscore; and
  - (ii) details of prior drug therapy for this condition [dosage, date of commencement and duration of therapy].

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to the application.

Applications for treatment of this condition must be received within 4 weeks of the endoscopy to confirm diagnosis.

The prescriber must exclude secondary causes of pouchitis, for example:

- (a) Ischaemia;
- (b) Crohn's disease (CD) or CD of the pouch;
- (c) Irritable pouch syndrome;
- (d) Predominant cuffitis;
- (e) Pouch stricture or pouch fistula;
- (f) Active infection;
- (g) NSAIDs;
- (h) Coeliac disease.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe chronic pouchitis

Treatment Phase: Initial 2 treatment (Recommencement of treatment after a break in biological medicine)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

## Clinical criteria:

- The treatment must be initiated in combination with standard of care antibiotic. The assessment of a patient's response to this initial course of treatment must be made after the third dose of vedolizumab so there is adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Application for authorisation of initial treatment must be in writing and must include:

- details of the proposed prescription; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the details of prior biological medicine therapy for this condition [date of commencement and duration of therapy].

The prescriber must have excluded secondary causes of pouchitis, for example:

- Ischaemia;
- Crohn's disease (CD) or CD of the pouch;
- Irritable pouch syndrome;
- Predominant cuffitis;
- Pouch stricture or pouch fistula;
- Active infection;
- NSAIDs;
- Coeliac disease.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## Authority required

Moderate to severe chronic pouchitis

Treatment Phase: Balance of Supply - Initial 1 treatment (new patient) and Initial 2 treatment (recommencement of treatment after a break in biological medicine)

## Clinical criteria:

- Patient must have received insufficient therapy with this drug under the Initial 1 treatment (new patient) restriction to complete 14 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 treatment (recommencement of treatment after a break in biological medicine) to complete 14 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks treatment available under the above treatment phases.

## Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## Authority required

Moderate to severe chronic pouchitis

Treatment Phase: Continuing treatment

## Clinical criteria:

- Patient must have previously received this drug as their most recent course of PBS-subsidised biological medicine for this condition, **AND**
- Patient must have demonstrated or sustained a partial or complete response, as determined by the treating clinician, to the most recent PBS-subsidised course of treatment with this drug for this condition.

## Treatment criteria:

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Patients who have failed to demonstrate a partial or complete response with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

An application for the continuing treatment must be made following the third dose with this drug and requested no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where an application is not made within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Moderate to severe chronic pouchitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2024, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis at least one year prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have had a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5 at the time of initiating treatment with this drug for this condition, **AND**
- Patient must have had a minimum endoscopic mPDAI sub-score of at least 2 at the time of initiating treatment with this drug for this condition, **AND**
- Patient must have had at least 3 recurrent episodes of pouchitis within the year prior to initiating treatment with this drug for this condition, each of which was treated with at least 2 weeks of antibiotic or other prescription therapy; OR
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must have been initiated in combination with standard of care antibiotic, **AND**
- Patient must have demonstrated a partial or complete response to treatment with this drug as determined by the treating clinician, for this condition if the patient has received non-PBS-subsidised treatment for the first three doses of induction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The assessment of a patient's response to this course of treatment must be made after the third dose of vedolizumab so there is adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

The application for authorisation of treatment must be in writing and must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and minimum endoscopic mPDAI sub-score; and
  - (ii) details of prior drug therapy for the condition [dosage, date of commencement and duration of therapy]; and
  - (iii) the date of commencement of this drug for this condition.

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to initiation with non-PBS-subsidised treatment with this drug.

The prescriber must have excluded secondary causes of pouchitis, for example:

- (a) Ischaemia;
- (b) Crohn's disease (CD) or CD of the pouch;
- (c) Irritable pouch syndrome;
- (d) Predominant cuffitis;
- (e) Pouch stricture or pouch fistula;
- (f) Active infection;
- (g) NSAIDs;
- (h) Coeliac disease.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### vedolizumab 300 mg injection, 1 vial

14679N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	2998.60	Entyvio [TK]

### Mammalian target of rapamycin (mTOR) kinase inhibitors

#### ■ EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

##### Authority required (STREAMLINED)

**9691**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

##### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

##### Authority required (STREAMLINED)

**9693**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

##### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

### everolimus 250 microgram tablet, 60

6459Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*324.69	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

### everolimus 500 microgram tablet, 60

6460B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*560.31	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

### everolimus 750 microgram tablet, 60

6461C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*1639.91	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

### everolimus 1 mg tablet, 60

9582H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*2170.35	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

#### ■ SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

##### Authority required (STREAMLINED)

**9914**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

##### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

### sirolimus 1 mg/mL oral liquid, 60 mL

6437T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*969.65	Rapamune [PF]

### sirolimus 500 microgram tablet, 100

9748C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*619.71	Rapamune [PF]

### sirolimus 1 mg tablet, 100

6436R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1223.71	Rapamune [PF]

**sirolimus 2 mg tablet, 100**

6457W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2398.79	Rapamune [PF]

*Complement inhibitors*

▪ **ECULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- Presenting clinical features, including history, acute treatment and medications;
- Results of testing for genetic mutations (if available);
- Family history of aHUS, especially in first-degree relatives;
- Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- Exclusion of alternative causes of TMA;
- History of renal or other organ transplant (if any);
- Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than  $30 \times 10^9/L$  and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

Evidence of active and progressing TMA is defined by the following:

- (1) a platelet count of less than  $150 \times 10^9/L$ ; and evidence of two of the following:
  - (i) presence of schistocytes on blood film;
  - (ii) low or absent haptoglobin;

HSD (Private)

- (iii) lactate dehydrogenase (LDH) above normal range;
- OR
- (2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; AND
- (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
  - (a) kidney impairment as demonstrated by one of the following:
    - (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
    - (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
    - (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
    - (iv) a renal biopsy consistent with aHUS;
  - (b) onset of TMA-related neurological impairment;
  - (c) onset of TMA-related cardiac impairment;
  - (d) onset of TMA-related gastrointestinal impairment;
  - (e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A detailed cover letter from the prescriber;
- (4) A measurement of body weight at the time of application;
- (5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;
- (6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - Balance of Supply;
- (7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;
- (8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;
- (9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10182X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5407.27	Soliris [XI]

▪ **ECULIZUMAB**

- Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.
- Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab
- Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Balance of Supply' patient must qualify under the 'First Continuing Treatment' criteria.
- Note** This Balance of Supply restriction will cease to operate from 5 years after the date specified in the clinical criteria.
- Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Balance of Supply (transition from non-PBS-subsidised treatment during induction phase)

**Clinical criteria:**

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have received insufficient quantity to complete the induction treatment phase, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10<sup>9</sup>/L)
- (iii) White Cell Count (x10<sup>9</sup>/L)
- (iv) Reticulocytes (x10<sup>9</sup>/L)
- (v) Neutrophils (x10<sup>9</sup>/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH)
- (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)

**eculizumab 300 mg/30 mL injection, 30 mL vial**

12864C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5407.27	Soliris [XI]

▪ **ECULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Services Australia will contact the prescriber by telephone after a written application has been submitted.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)  
Treatment Phase: Initial treatment - Balance of Supply

**Clinical criteria:**

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion, and must have been submitted to Services Australia within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)  
Treatment Phase: Recommencement - Balance of Supply

**Clinical criteria:**

- Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10192K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	5407.27	Soliris [XI]

▪ **ECULIZUMAB**

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia



Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - initial 1 (new patient) induction doses

**Clinical criteria:**

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10<sup>9</sup>/L)
- (iii) White Cell Count (x10<sup>9</sup>/L)
- (iv) Reticulocytes (x10<sup>9</sup>/L)
- (v) Neutrophils (x10<sup>9</sup>/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH)
- (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)

**Clinical criteria:**

- Patient must be planning pregnancy; OR
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition, **AND**
- The treatment must not be in combination with any of (i) ravulizumab, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised pegcetacoplan - induction doses

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition, **AND**
- Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition, **AND**
- Patient must have developed resistance or intolerance to pegcetacoplan, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

12896R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	..	..	*42917.47	Soliris [XI]

▪ **ECULIZUMAB**

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)

**Clinical criteria:**

- Patient must be planning pregnancy; OR
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with ravulizumab for this condition, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase

**Clinical criteria:**

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**

- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets ( $\times 10^9/L$ )
- White Cell Count ( $\times 10^9/L$ )
- Reticulocytes ( $\times 10^9/L$ )
- Neutrophils ( $\times 10^9/L$ )
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

**Note** This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 2 (transition from LSDP-funded eculizumab)

**Clinical criteria:**

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR

- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets (x10<sup>9</sup>/L)
- White Cell Count (x10<sup>9</sup>/L)
- Reticulocytes (x10<sup>9</sup>/L)
- Neutrophils (x10<sup>9</sup>/L)
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets (x10<sup>9</sup>/L)
- White Cell Count (x10<sup>9</sup>/L)
- Reticulocytes (x10<sup>9</sup>/L)
- Neutrophils (x10<sup>9</sup>/L)
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place)

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**eculizumab 300 mg/30 mL injection, 30 mL vial**

12899X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*32200.29	Soliris [XI]

▪ **ECULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised eculizumab under the initial treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the initial treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 80 weeks of eculizumab treatment in total under this restriction; OR
- Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and
- (2) One of the following:
  - a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
  - b) an eGFR within +/- 25% from baseline; or

HSD (Private)

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

- (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted;
- (5) A family history of aHUS, if applicable;
- (6) A history of kidney transplant if applicable (especially if required due to aHUS);
- (7) An inclusion of the individual consequences of recurrent disease, if applicable;
- (8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;
- (9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;
- (10) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

A maximum of up to 80 weeks of eculizumab treatment (or 104 weeks if switching C5 inhibitors during the course of initial and continuing treatment) is allowed under this restriction, however an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

## **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

### **Clinical criteria:**

- Patient must have received PBS-subsidised eculizumab under the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the extended continuing treatment phase for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and
- (2) One of the following:

- a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
- b) an eGFR within +/- 25% from baseline; or
- c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

- (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted;
- (5) A family history of aHUS, if applicable;
- (6) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable;
- (7) A history of kidney transplant, if applicable (especially if required due to aHUS);
- (8) An inclusion of the individual consequences of recurrent disease;
- (9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment;
- (10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application;
- (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;
- (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

#### **Clinical criteria:**

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; **AND** (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10<sup>9</sup>/L); OR (iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and
- (2) One of the following:
  - a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
  - b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

- (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted;
- (5) A family history of aHUS if applicable;
- (6) A history of multiple episodes of aHUS following the treatment break, if applicable;
- (7) A history of kidney transplant if applicable (especially if required due to aHUS);
- (8) An inclusion of the individual consequences of recurrent disease;
- (9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
- (10) Evidence that the patient has had a treatment response to their previous treatment with eculizumab;
- (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;
- (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** A raise in LDH alone is not a sufficient reason to recommence a C5 inhibitor, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider recommencement of C5 inhibitor treatment.

**Note** Kidney transplantation/dialysis is not a contraindication to recommencement of C5 inhibitor treatment.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

#### **Clinical criteria:**

- Patient must have received PBS-subsidised eculizumab under the recommencement of treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing recommencement of treatment phase for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 24 weeks of treatment with eculizumab per continuing treatment course authorised under this restriction.

#### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

- a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
- b) an eGFR within +/- 25% from baseline; or
- c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:



- (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.
- The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).
- The authority application must be in writing and must include all of the following:
- (1) A completed authority prescription form(s);
  - (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
  - (3) A measurement of body weight at the time of application;
  - (4) Results of genetic testing, if not previously submitted;
  - (5) A family history of aHUS, if applicable;
  - (6) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable;
  - (7) A history of kidney transplant if applicable (especially if required due to aHUS);
  - (8) An inclusion of the individual consequences of recurrent disease, if applicable;
  - (9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;
  - (10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;
  - (11) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Switch from PBS-subsidised ravulizumab (all phases) - loading dose

**Clinical criteria:**

- Patient must have previously received PBS-subsidised ravulizumab under the 'Initial treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Extended continuing treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing recommencement of treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Grandfather (transitioning from non-PBS to PBS-subsidised treatment)' restriction for this condition, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 24 weeks of C5 inhibitor supply for this current treatment phase under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

The application must indicate the most recent treatment phase that the patient is switching from.

For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 24 weeks of treatment, according to the specified dosage in the approved Product Information (PI). An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength

requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10194M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	5407.27	Soliris [XI]

▪ **PEGCETACOPLAN**

**Caution** This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

**Note** Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab post pregnancy or from PBS-subsidised Complement 5 (C5) inhibitor for reasons other than post pregnancy

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 3 (switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)' criteria; OR
- Patient must have received prior PBS-subsidised treatment with at least one C5 inhibitor and returning to pegcetacoplan treatment for reasons other than post pregnancy, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets ( $\times 10^9/L$ )
- White Cell Count ( $\times 10^9/L$ )
- Reticulocytes ( $\times 10^9/L$ )
- Neutrophils ( $\times 10^9/L$ )
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place)

For the purposes of family planning, patient may qualify under this treatment phase more than once. To return to pegcetacoplan treatment for reasons other than post pregnancy, patient may qualify under this treatment phase once only in

HSD (Private)

any 12 consecutive months. Where long-term continuing PBS-subsidised treatment with pegcetacoplan is planned, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria of pegcetacoplan.

**pegcetacoplan 1.08 g/20 mL injection, 20 mL vial**

13191G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4392.53	Empaveli [ZO]

▪ **PEGCETACOPLAN**

**Caution** This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

**Note** Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)  
Treatment Phase: Initial treatment (new patient)

**Clinical criteria:**

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months, **AND**
- Patient must have experienced an inadequate response to a complement 5 (C5) inhibitor demonstrated by a haemoglobin level of less than 105 g/L; OR
- Patient must be intolerant to C5 inhibitors as determined by the treating physician, **AND**
- Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred, **AND**
- The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

**Population criteria:**

- Patient must be at least 18 years of age.
- The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
  - (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
- At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.
- At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:
- (i) Haemoglobin (g/L)
  - (ii) Platelets ( $\times 10^9/L$ )
  - (iii) White Cell Count ( $\times 10^9/L$ )
  - (iv) Reticulocytes ( $\times 10^9/L$ )
  - (v) Neutrophils ( $\times 10^9/L$ )
  - (vi) Granulocyte clone size (%)
  - (vii) Lactate Dehydrogenase (LDH)
  - (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
  - (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)

**pegcetacoplan 1.08 g/20 mL injection, 20 mL vial**

13196M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4392.53	Empaveli [ZO]

## ▪ PEGCETACOPLAN

**Caution** This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

**Note** Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First continuing treatment

### **Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction, **AND**
- The treatment must not be in combination with a Complement 5 (C5) inhibitor.

### **Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets ( $\times 10^9/L$ )
- White Cell Count ( $\times 10^9/L$ )
- Reticulocytes ( $\times 10^9/L$ )
- Neutrophils ( $\times 10^9/L$ )
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place)

### **Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must not be in combination with a Complement 5 (C5) inhibitor.

### **Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

**pegcetacoplan 1.08 g/20 mL injection, 20 mL vial**

13197N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4392.53	Empaveli [ZO]

▪ **RAVULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** See the following article/website for details on Expanded Disability Status Scale (EDSS):

<https://www.ncbi.nlm.nih.gov/books/NBK222389/>.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Initial treatment - loading dose

**Clinical criteria:**

- Patient must have a confirmed diagnosis of NMOSD with aquaporin-4 immunoglobulin G auto-antibody (AQP4-IgG), **AND**
- Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must have had at least one relapse in the last 12 months, **AND**
- Patient must have experienced the most recent relapse while receiving treatment with rituximab; OR
- Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; OR
- Patient must have a documented contraindication to rituximab therapy, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for a single loading dose for induction therapy, according to the specified dosage in the approved Product Information (PI). Refer to the approved PI for patient weight ranges for the 100 mg/mL doses (consisting of 300 mg in 3 mL and 1.1 g in 11 mL vials).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

The authority application must be in writing and must include all of the following:

- (1) details of the proposed authority prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the patient's Expanded Disability Status Scale (EDSS) score; and
  - (ii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy), or details of contraindications or developed intolerances necessitating treatment withdrawal.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**ravulizumab 1.1 g/11 mL injection, 11 mL vial**

14745C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	24153.78	Ultomiris [XI]

**ravulizumab 300 mg/3 mL injection, 3 mL vial**

14746D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6622.79	Ultomiris [XI]

## ▪ RAVULIZUMAB

**Note** WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

### Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new patient) induction dose

#### **Clinical criteria:**

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

#### **Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

(i) Haemoglobin (g/L)

(ii) Platelets (x10<sup>9</sup>/L)

(iii) White Cell Count (x10<sup>9</sup>/L)

(iv) Reticulocytes (x10<sup>9</sup>/L)

(v) Neutrophils (x10<sup>9</sup>/L)

(vi) Granulocyte clone size (%)

(vii) Lactate Dehydrogenase (LDH)

(viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory

(ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

### Authority required

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose

#### **Clinical criteria:**

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab, **AND**

- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets (x10<sup>9</sup>/L)
- White Cell Count (x10<sup>9</sup>/L)
- Reticulocytes (x10<sup>9</sup>/L)
- Neutrophils (x10<sup>9</sup>/L)
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab - induction dose

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised pegcetacoplan - induction doses

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition, **AND**
- Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition, **AND**
- Patient must have developed resistance or intolerance to pegcetacoplan, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

**ravulizumab 1.1 g/11 mL injection, 11 mL vial**

12901B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	24153.78	Ultomiris [XI]

**ravulizumab 300 mg/3 mL injection, 3 mL vial**

12841W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6622.79	Ultomiris [XI]

▪ **RAVULIZUMAB**

**Note** WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather (transition from non-PBS-subsidised treatment)

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR



- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets ( $\times 10^9/L$ )
- White Cell Count ( $\times 10^9/L$ )
- Reticulocytes ( $\times 10^9/L$ )
- Neutrophils ( $\times 10^9/L$ )
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

**Note** This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets ( $\times 10^9/L$ )
- White Cell Count ( $\times 10^9/L$ )
- Reticulocytes ( $\times 10^9/L$ )
- Neutrophils ( $\times 10^9/L$ )
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place)

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

### ravulizumab 1.1 g/11 mL injection, 11 mL vial

12897T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	24153.78	Ultomiris [XI]

### ravulizumab 300 mg/3 mL injection, 3 mL vial

12895Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6622.79	Ultomiris [XI]

## ■ RAVULIZUMAB

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** See the following article/website for details on Expanded Disability Status Scale (EDSS): <https://www.ncbi.nlm.nih.gov/books/NBK222389/>.

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

**Note** Special Pricing Arrangements apply.

### Authority required

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must not have experienced a relapse while receiving treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### **Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2025, **AND**
- Patient must have a confirmed diagnosis of NMOSD with AQP4-IgG prior to commencing treatment with this drug, **AND**
- Patient must have a recorded baseline Expanded Disability Status Scale (EDSS) score of no higher than 7 prior to commencing treatment with this drug, **AND**
- Patient must have had at least one relapse in the 12 months prior to commencing treatment with this drug for this condition, **AND**
- Patient must have received treatment with rituximab immediately prior to the most recent relapse prior to initiation of ravulizumab; OR
- Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; OR
- Patient must have a documented contraindication to rituximab therapy, **AND**
- Patient must have a current Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must not have experienced a relapse while receiving treatment with this drug for this condition, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

The authority application must be in writing and must include all of the following:

- (1) details of the proposed authority prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the patient's baseline Expanded Disability Status Scale (EDSS) score before commencement with this drug for this condition; and
  - (ii) the patient's current Expanded Disability Status Scale (EDSS) score; and
  - (iii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy), or details of contraindications or developed intolerances necessitating treatment withdrawal.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ravulizumab 1.1 g/11 mL injection, 11 mL vial**

14776Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	24153.78	Ultomiris [XI]

**ravulizumab 300 mg/3 mL injection, 3 mL vial**

14771K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6622.79	Ultomiris [XI]

▪ **RAVULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 2 weeks of treatment, according to the specified dosage in the approved Product Information (PI). An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

## **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Initial (new patient) loading dose

### **Clinical criteria:**

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than  $30 \times 10^9/L$  and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Evidence of active and progressing TMA is defined by the following:

(1) A platelet count of less than  $150 \times 10^9/L$ ; and evidence of at least two of the following:

- (i) presence of schistocytes on blood film;
- (ii) low or absent haptoglobin;
- (iii) lactate dehydrogenase (LDH) above normal range; or

(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and

(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one or more of the following:

- (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment;
- (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment;
- (iii) a sCr of greater than the age-appropriate ULN in paediatric patients;
- (iv) a renal biopsy consistent with aHUS;
- (b) onset of TMA-related neurological impairment;
- (c) onset of TMA-related cardiac impairment;
- (d) onset of TMA-related gastrointestinal impairment;
- (e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.

The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A detailed cover letter from the prescriber;
- (4) A measurement of body weight at the time of application;
- (5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;
- (6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result

must be submitted to Services Australia within 13 days of commencement of ravulizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised C5 inhibitor treatment, under Initial balance of supply;

(7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;

(8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;

(9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Two authority prescription forms will be required to cover for the 26 weeks of initial therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- a) Presenting clinical features, including history, acute treatment and medications;
- b) Results of testing for genetic mutations (if available);
- c) Family history of aHUS, especially in first-degree relatives;
- d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Switch from PBS-subsidised eculizumab (all phases) - loading dose

**Clinical criteria:**

- Patient must have previously received PBS-subsidised eculizumab under the 'Initial treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised eculizumab under the 'Continuing treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised eculizumab under the 'Extended continuing treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised eculizumab under the 'Continuing recommencement of treatment' restriction for this condition, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**

• Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

The application must indicate the most recent treatment phase that the patient is switching from.

For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have demonstrated treatment response to previous treatment with a PBS-subsidised C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; **AND** (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10<sup>9</sup>/L); OR (iii) TMA-related organ impairment including on recent biopsy.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR

- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
  - Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.
- This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS if applicable;

(6) A history of multiple episodes of aHUS following the treatment break, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(10) Evidence that the patient has had a treatment response to their previous treatment with a C5 inhibitor;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Two authority prescription forms will be required to cover for the 26 weeks of commencement therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.

**Note** A raise in LDH alone is not a sufficient reason to recommence a C5 inhibitor, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider commencement of C5 inhibitor treatment.

**Note** Kidney transplantation/dialysis is not a contraindication to commencement of C5 inhibitor treatment.

**ravulizumab 1.1 g/11 mL injection, 11 mL vial**

13802K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	24153.78	Ultomiris [XI]

**ravulizumab 300 mg/3 mL injection, 3 mL vial**

13791W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6622.79	Ultomiris [XI]

▪ **RAVULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Balance of Supply - maintenance doses

**Clinical criteria:**

- Patient must have received PBS-subsidised loading dose of ravulizumab for this condition for this current treatment phase, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must have received insufficient therapy to complete the maximum allowable treatment under their specified treatment phase, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the relevant treatment phase.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion and must have been submitted to Services Australia within 13 days of commencement of ravulizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment. An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** Services Australia will contact the prescriber by telephone after a written application has been submitted.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised ravulizumab under the initial treatment phase for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the grandfather restriction for this condition, **AND**
- Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 72 weeks of ravulizumab treatment in total under this restriction; OR
- Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**

- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and
- (2) One of the following:
  - a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
  - b) an eGFR within +/- 25% from baseline; or
  - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

- (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted;
- (5) A family history of aHUS, if applicable;
- (6) A history of kidney transplant if applicable (especially if required due to aHUS);
- (7) An inclusion of the individual consequences of recurrent disease, if applicable;
- (8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;
- (9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;
- (10) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended continuing treatment

### **Clinical criteria:**

- Patient must have received PBS-subsidised ravulizumab under the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the extended continuing treatment phase for this condition, **AND**
- Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with ravulizumab, **AND**



- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before commencing ravulizumab treatment, if applicable;

(7) A history of kidney transplant, if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment;

(10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Recommencement treatment' restriction for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Continuing recommencement treatment' restriction for this condition, **AND**

- Patient must have demonstrated ongoing treatment response to 'Recommendation of treatment' with a C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
  - Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
  - Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.
- This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before recommencing ravulizumab treatment, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease, if applicable;

(9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(11) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS supply was commenced, the patient: (i) had active and progressing thrombotic microangiopathy (TMA) caused by aHUS; (ii) had ADAMTS-13 activity of greater than or equal to 10% on a blood sample

not confounded by any plasma exchange or infusion; (iii) had a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days of commencing ravulizumab treatment; (iv) had clinical features of active organ damage or impairment, **AND**

- Patient must have demonstrated ongoing treatment response with ravulizumab for this condition if received at least 26 weeks of initial non-PBS-subsidised therapy, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition if they have received at least 26 weeks of initial non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Evidence of active and progressing TMA is defined by the following:

(1) A platelet count of less than  $150 \times 10^9/L$ ; and evidence of at least two of the following:

- (i) presence of schistocytes on blood film;
- (ii) low or absent haptoglobin;
- (iii) lactate dehydrogenase (LDH) above normal range; or

(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and

(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one or more of the following:

- (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment;
- (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment;
- (iii) a sCr of greater than the age-appropriate ULN in paediatric patients;
- (iv) a renal biopsy consistent with aHUS;
- (b) onset of TMA-related neurological impairment;
- (c) onset of TMA-related cardiac impairment;
- (d) onset of TMA-related gastrointestinal impairment;
- (e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.

The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A detailed cover letter from the prescriber;
- (4) A measurement of body weight at the time of application;
- (5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay;
- (6) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days of initiating treatment with non-PBS-subsidised ravulizumab;
- (7) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of commencement of non-PBS-subsidised ravulizumab;
- (8) For patients who have received at least 26 weeks of ravulizumab treatment, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for the balance of the current treatment phase. 8 weeks of treatment and up to 2 repeats according to the specified dosage in the approved Product Information (PI) may be sought.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- a) Presenting clinical features, including history, acute treatment and medications;
- b) Results of testing for genetic mutations (if available);
- c) Family history of aHUS, especially in first-degree relatives;
- d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- e) Exclusion of alternative causes of TMA;  
 f) History of renal or other organ transplant (if any);  
 g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

### ravulizumab 1.1 g/11 mL injection, 11 mL vial

13784L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	24153.78	Ultomiris [XI]

### ravulizumab 300 mg/3 mL injection, 3 mL vial

13786N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6622.79	Ultomiris [XI]

### Other immunosuppressants

#### ▪ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatrix - Viatrix Care.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

#### **Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 2 cycles under this restriction.

### lenalidomide 10 mg capsule, 21

12050F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	864.24	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 15 mg capsule, 21

12011E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1039.10	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 25 mg capsule, 21

12037M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1344.97	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 5 mg capsule, 21

12038N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	661.75	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 20 mg capsule, 21

14609X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1315.36	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

#### ▪ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatrix - Viatrix Care.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**lenalidomide 10 mg capsule, 21**

12060R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	864.24	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 15 mg capsule, 21**

12020P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1039.10	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 25 mg capsule, 21**

12068E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1344.97	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Lenalidomide Sandoz [SZ]  
Revlimid [BQ]

Lenalidomide Viatris [AF]

## lenalidomide 5 mg capsule, 21

12071H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	661.75	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 20 mg capsule, 21

14631C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1315.36	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

## ■ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone

### Treatment criteria:

- Patient must be undergoing concurrent treatment with elotuzumab obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

## lenalidomide 10 mg capsule, 21

12980E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	864.24	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 15 mg capsule, 21

12986L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1039.10	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 25 mg capsule, 21

12993W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1344.97	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 5 mg capsule, 21

12984J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	661.75	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 20 mg capsule, 21

14583M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1315.36	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

## ■ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

### Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with carfilzomib obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

**lenalidomide 10 mg capsule, 21**

13658W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	864.24	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 15 mg capsule, 21**

13657T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1039.10	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 25 mg capsule, 21**

13660Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1344.97	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 5 mg capsule, 21**

13642B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	661.75	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 20 mg capsule, 21**

14582L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1315.36	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

▪ **LENALIDOMIDE**

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Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR

6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR  
 7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.  
 Classification of a patient as red blood cell transfusion dependent requires that:

- (i) the patient has been transfused within the last 8 weeks; and
- (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and
- (b) details (date, unique identifying number/code or provider number) of the full blood examination report; and
- (c) details (date, unique identifying number/code or provider number) of the pathology report and details of the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
- (d) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red blood cell units transfused in the 4 and 6 months preceding the date of this application.

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or at least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The condition must not have progressed to acute myeloid leukaemia.

The first authority application for continuing supply must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone.

The following evidence of response must be provided at each application:

- (i) a haemoglobin level taken within the last 4 weeks; and
- (ii) the date of the last transfusion; and
- (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application;

All reports must be documented in the patient's medical records.

For first continuing applications, if the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**lenalidomide 10 mg capsule, 21**

2796E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	864.24	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 5 mg capsule, 21**

2798G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	661.75	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

**Clinical criteria:**



- The condition must be newly diagnosed, **AND**
  - The condition must be confirmed by a histological diagnosis, **AND**
  - Patient must be ineligible for a primary stem cell transplantation, **AND**
  - The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.
- The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:
- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and
  - (2) confirmation of ineligibility for prior stem cell transplant; and
  - (3) nomination of which disease activity parameters will be used to assess response.
- To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:
- (a) the level of serum monoclonal protein; or
  - (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
  - (c) the serum level of free kappa and lambda light chains; or
  - (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
  - (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
  - (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
  - (g) if present, the level of hypercalcaemia, corrected for albumin concentration.
- As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.
- All reports must be documented in the patient's medical records.
- If the application is submitted through HPOS form upload or mail, it must include:
- (i) A completed authority prescription form; and
  - (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
  - The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.
- Progressive disease is defined as at least 1 of the following:
- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
  - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
  - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
  - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
  - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
  - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
  - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).
- Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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### lenalidomide 10 mg capsule, 21

11063G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	864.24	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 15 mg capsule, 21

11042E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1039.10	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 25 mg capsule, 21

11055W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1344.97	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 5 mg capsule, 21

11036W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	661.75	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 20 mg capsule, 21

14624Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1315.36	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

## ■ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatrix - Viatrix Care.

### Authority required

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

### **Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and
- (2) the date the autologous stem cell transplant was performed; and
- (3) nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as monotherapy.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**lenalidomide 5 mg capsule, 28**

11966T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	879.44	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 10 mg capsule, 28**

11969Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1145.55	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 15 mg capsule, 28**

11965R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1369.73	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatrix - Viatrix Care.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**lenalidomide 10 mg capsule, 14**

12004T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	579.05	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 15 mg capsule, 14**

12069F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	695.62	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 25 mg capsule, 14**

12018M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	907.44	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 5 mg capsule, 14**

12058P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	444.06	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 20 mg capsule, 14**

14615F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	886.91	Lenalide [JU]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatrix - Viatrix Care.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and
- (2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and
- (3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and
- (4) details of the basis of the diagnosis of progressive disease or failure to respond; and
- (5) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; OR
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**lenalidomide 10 mg capsule, 21**

9643M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	864.24	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 15 mg capsule, 21**

9644N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1039.10	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 25 mg capsule, 21**

9645P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1344.97	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 5 mg capsule, 21**

9642L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	661.75	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 20 mg capsule, 21**

14610Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1315.36	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

▪ **POMALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalyst - i-access program; Pomalidomide Sandoz - Pregnancy Prevention Program.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**pomalidomide 3 mg capsule, 14**

12668R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1711.59	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [BQ]

**pomalidomide 4 mg capsule, 14**

12661J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2265.89	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [BQ]

**pomalidomide 1 mg capsule, 14**

13813B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	655.46	Pomolide [JU]

**pomalidomide 2 mg capsule, 14**

13812Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	1157.28	Pomolide [JU]

## ▪ POMALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalyst - i-access program; Pomalidomide Sandoz - Pregnancy Prevention Program.

### Authority required

Multiple myeloma

Treatment Phase: Initial treatment - dual therapy in combination with dexamethasone

### **Clinical criteria:**

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and
- (2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Multiple myeloma

Treatment Phase: Continuing treatment - dual therapy in combination with dexamethasone

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:



- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  
 (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  
 (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  
 (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  
 (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  
 (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  
 (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### pomalidomide 4 mg capsule, 21

10386P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	3374.50	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [BQ]

#### pomalidomide 1 mg capsule, 21

13814C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	978.85	Pomalidomide Sandoz [SZ]	Pomolide [JU]

#### pomalidomide 3 mg capsule, 21

10417G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2543.05	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [BQ]

#### pomalidomide 2 mg capsule, 21

13811X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1711.59	Pomalidomide Sandoz [SZ]	Pomolide [JU]

### ■ THALIDOMIDE

**Caution** Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

#### Authority required (STREAMLINED)

**9290**

Multiple myeloma

#### thalidomide 100 mg capsule, 28

9684Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*1110.05	Thalomid [BQ]

#### thalidomide 50 mg capsule, 28

6469L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*1110.07	Thalomid [BQ]

### ■ MUSCULO-SKELETAL SYSTEM

#### ■ MUSCLE RELAXANTS

##### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

*Other centrally acting agents*

#### ■ BACLOFEN

#### Authority required (STREAMLINED)

**9562**

Severe chronic spasticity

#### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

#### Authority required (STREAMLINED)

**9525**

Severe chronic spasticity

#### Clinical criteria:

## MUSCULO-SKELETAL SYSTEM

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required (STREAMLINED)**

**9638**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required (STREAMLINED)**

**9606**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

**baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule**

11194E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*644.51	Sintetica Baclofen Intrathecal [BZ]

### ■ BACLOFEN

**Note** Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**9488**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

**Authority required (STREAMLINED)**

**9637**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required (STREAMLINED)**

**9489**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required (STREAMLINED)**

**9524**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

**baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules**

11128Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	801.88	<sup>a</sup> Sintetica Baclofen Intrathecal [BZ]

**baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule**

6284R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*801.87	<sup>a</sup> Bacthecal [DZ]	<sup>a</sup> Lioresal Intrathecal [NV]

### ■ DRUGS FOR TREATMENT OF BONE DISEASES

#### DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION

##### *Bisphosphonates*

## ■ PAMIDRONATE DISODIUM

### Authority required (STREAMLINED)

**9234**

Hypercalcaemia of malignancy

#### Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

### pamidronate disodium 15 mg/5 mL injection, 5 mL vial

6286W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	2	..	*67.91	Pamisol [PF]

### pamidronate disodium 30 mg/10 mL injection, 10 mL vial

6287X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*67.93	Pamisol [PF]

### pamidronate disodium 60 mg/10 mL injection, 10 mL vial

6288Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	67.93	Pamisol [PF]

## ■ PAMIDRONATE DISODIUM

### Authority required (STREAMLINED)

**9234**

Hypercalcaemia of malignancy

#### Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

### Authority required (STREAMLINED)

**9335**

Multiple myeloma

### Authority required (STREAMLINED)

**9315**

Bone metastases

#### Clinical criteria:

- The condition must be due to breast cancer.

### pamidronate disodium 90 mg/10 mL injection, 10 mL vial

6289B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	95.56	Pamisol [PF]

## ■ ZOLEDRONIC ACID

### Authority required (STREAMLINED)

**14729**

Adjuvant management of breast cancer

#### Population criteria:

- Patient must be post-menopausal.

#### Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months.

### zoledronic acid 4 mg/5 mL injection, 5 mL vial

13772W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	72.23	<sup>a</sup> DEZTRON [DZ] <sup>a</sup> Zoledronic Acid Accord [OC]	<sup>a</sup> Zoledronate-DRLA 4 [RZ]

## ■ ZOLEDRONIC ACID

### Authority required (STREAMLINED)

**9268**

Multiple myeloma

### Authority required (STREAMLINED)

**9328**

Bone metastases

#### Clinical criteria:

- The condition must be due to breast cancer.

### Authority required (STREAMLINED)

**9304**

Bone metastases

#### Clinical criteria:

- The condition must be due to castration-resistant prostate cancer.

### Authority required (STREAMLINED)

**9317**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**zoledronic acid 4 mg/5 mL injection, 5 mL vial**

6371H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	72.23	<sup>a</sup> APO-Zoledronic Acid [TX] <sup>a</sup> Zoledronate-DRLA 4 [RZ] <sup>a</sup> Zometa [SA]	<sup>a</sup> DEZTRON [DZ] <sup>a</sup> Zoledronic Acid Accord [OC]

*Other drugs affecting bone structure and mineralization*

▪ **BUROSUMAB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** Special Pricing Arrangements apply.

**Authority required**

X-linked hypophosphataemia

Treatment Phase: Initial treatment - New patient

**Clinical criteria:**

- Patient must have a documented confirmation of PHEX pathogenic variant; OR
- Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following: (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.
- At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

**Authority required**

X-linked hypophosphataemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels, **AND**
- Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.
- Where adequate response to treatment with this drug cannot be demonstrated, the treating physician must confirm that continuing therapy has been determined to be clinically required by a second specialist physician with expertise in the treatment of X-linked hypophosphataemia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

**burosumab 30 mg/mL injection, 1 mL vial**

13154H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	12045.67	Crysvita [KO]

**burosumab 20 mg/mL injection, 1 mL vial**

13136J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	8046.67	Crysvita [KO]

**burosumab 10 mg/mL injection, 1 mL vial**

13163T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4047.67	Crysvita [KO]

## OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

### OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

#### *Other drugs for disorders of the musculo-skeletal system*

#### ■ NUSINERSEN

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing

#### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

#### **Population criteria:**

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

#### **nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

11476B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	104548.67	Spinraza [BD]

#### ■ NUSINERSEN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Note** Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. **Muscle & Nerve** 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. **PLoS ONE** 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. **American Journal of Respiratory and Critical Care Medicine** 166(1), pp 111-117

The National Health Foundation of Australia has 6MWT test standardised instructions and recording forms located at: <https://www.heartonline.org.au/resources/documents-and-links#exercise>

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. **Muscle & Nerve** 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. **Neurology** April (15 Supplement) P4.452

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

**Clinical criteria:**

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HF MSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

13045N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	104548.67	Spinraza [BD]

▪ **NUSINERSEN**

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

**Clinical criteria:**

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

13091B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	104548.67	Spinraza [BD]

## ■ NUSINERSEN

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

### Authority required

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing

### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

### **Population criteria:**

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

### **nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

14090N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	104548.67	Spinraza [BD]

## ■ NUSINERSEN

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

### Authority required

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment - Loading doses

### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must be untreated with gene therapy.

**Population criteria:**

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:

- Onset before 6 months of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- Onset between 6 and 18 months; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Weakness in trunk righting/derotation; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- Onset between 18 months and 3 years of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Application for authorisation of initial treatment must be in writing and must include:

- a completed authority prescription form; and
- a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
  - specification of SMA type (I, II or IIIa); and
  - sign(s) and symptom(s) that the patient has experienced; and
  - patient's age at the onset of sign(s) and symptom(s).

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

11472T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104548.67	Spinraza [BD]

▪ **NUSINERSEN**

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001



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

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

**Note** Special Pricing Arrangements apply.

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

**Authority required**

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 1 or 2 copies of the SMN2 gene - Loading doses

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must be untreated with gene therapy.

**Population criteria:**

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) a completed authority prescription form; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

12176W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104548.67	Spinraza [BD]

▪ **NUSINERSEN**

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

**Authority required**

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene - Loading doses

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must be untreated with gene therapy.

**Population criteria:**

- Patient must be aged under 36 months prior to commencing treatment.
- Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:
- (a) a completed authority prescription form; and
  - (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
    - (i) confirmation of genetic diagnosis of SMA; and
    - (ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

14096X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104548.67	Spinraza [BD]

▪ **NUSINERSEN**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in an adult who did not initiate PBS subsidy during childhood

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

**Population criteria:**

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood, **AND**
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19<sup>th</sup> birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Failure to gain weight appropriate for age,
- (vi) Any active denervation or chronic neurogenic changes found on electromyography,
- (vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,

- (2) which of the above (i to vii) (at least 1) were present during childhood,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

**Authority required**

Spinal muscular atrophy (SMA)  
 Treatment Phase: Changing the prescribed therapy

**Treatment criteria:**

- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19<sup>th</sup> birthday, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- Patient must be untreated with gene therapy, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.

**Note** Subsequent changes in the prescribed drug where applicable are to occur under the 'Continuing treatment' phase listing of the drug that therapy is changing to.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

13064N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104548.67	Spinraza [BD]

▪ **NUSINERSEN**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)  
 Treatment Phase: Initial PBS-subsidised treatment in a child

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

**Population criteria:**

- Patient must be of an age that is prior to their 19<sup>th</sup> birthday at the time of this authority application, **AND**
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday (SMA type IIIB/IIIC).

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**

- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Any active denervation or chronic neurogenic changes found on electromyography,
- (vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,
- (2) which of the above (i to vi) were present after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Changing the prescribed therapy

**Treatment criteria:**

- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19<sup>th</sup> birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- Patient must be untreated with gene therapy, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.

**Note** Subsequent changes in the prescribed drug where applicable are to occur under the 'Continuing treatment' phase listing of the drug that therapy is changing to.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

13111C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104548.67	Spinraza [BD]

## ▪ RISDIPLAM

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment

### **Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

### **Clinical criteria:**

- Patient must be untreated with gene therapy.

### **Population criteria:**

- Patient must be 18 years of age or under.  
Defined signs and symptoms of type I SMA are:
  - i) Onset before 6 months of age; and
  - ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
  - iii) Proximal weakness; or
  - iv) Hypotonia; or
  - v) Absence of deep tendon reflexes; or
  - vi) Failure to gain weight appropriate for age; or
  - vii) Any active chronic neurogenic changes; or
  - viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- i) Onset between 6 and 18 months; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Weakness in trunk righting/derotation; or
- v) Hypotonia; or
- vi) Absence of deep tendon reflexes; or
- vii) Failure to gain weight appropriate for age; or
- viii) Any active chronic neurogenic changes; or
- ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- i) Onset between 18 months and 3 years of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Application for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
  - i) specification of SMA type (I, II or IIIa); and
  - (ii) sign(s) and symptom(s) that the patient has experienced; and
  - (iii) patient's age at the onset of sign(s) and symptom(s).

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

12610Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	10890.56	Evrysdi [RO]

▪ **RISDIPLAM**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

**Population criteria:**

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

14639L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	10890.56	Evrysdi [RO]

## ▪ RISDIPLAM

**Note** The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene)

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

### **Population criteria:**

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

### **risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

12609P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	10890.56	Evrysdi [RO]

## ▪ RISDIPLAM

**Note** For the next authority application after this application, continue treatment through the 'Treatment phase: Continuing treatment' under the indication: 'Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

## **Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with Type 1 SMA

### **Clinical criteria:**

- Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this: (i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples), **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition.

### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type.

### **Population criteria:**

- Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for symptomatic Type 1 SMA.

Definition:

Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.

0. Absence of developmental states (1 to 9) listed below:

1. Rolls from side to side on back;
2. Child holds head erect for at least 3 seconds unsupported;
3. Sitting, but with assistance;
4. Sitting without assistance:
  - (a) Child sits up straight with the head erect for at least 10 seconds;
  - (b) Child does not use arms or hands to balance body or support position.

5. Hands and knees crawling:

- (a) Child alternately moves forward or backwards on hands and knees;
- (b) The stomach does not touch the supporting surface;
- (c) There are continuous and consecutive movements at least 3 in a row.

6. Standing with assistance:

- (a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object;
- (b) The body does not touch the stable object, and the legs support most of the body weight;
- (c) Child thus stands with assistance for at least 10 seconds.

7. Standing alone:

- (a) Child stands in upright position on both feet (not on the toes) with the back straight;
- (b) The leg supports 100% of the child's weight;
- (c) There is no contact with a person or object;
- (d) Child stands alone for at least 10 seconds.

8. Walking with assistance:

- (a) Child is in an upright position with the back straight;
- (b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;
- (c) One leg moves forward while the other supports part of the body weight;
- (d) Child takes at least 5 steps in this manner.

9. Walking alone:

- (a) Child takes at least 5 steps independently in upright position with the back straight;
- (b) One leg moves forward while the other supports most of the body weight;
- (c) There is no contact with a person or object.

Confirm which developmental state has regressed by: (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i)).

Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.



The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

### risdiplam 750 microgram/mL powder for oral liquid, 80 mL

12959C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	10890.56	Evrysdi [RO]

#### ■ RISDIPLAM

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment with this drug of pre-symptomatic spinal muscular atrophy (SMA)

#### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA.

#### **Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The condition must be pre-symptomatic, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- Patient must be untreated with gene therapy.

#### **Population criteria:**

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;

# MUSCULO-SKELETAL SYSTEM

3 units where (iv) applies.

## risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13647G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	10890.56	Evrysdi [RO]

### ▪ RISDIPLAM

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos).

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

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

**Note** Special Pricing Arrangements apply.

#### Authority required

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

#### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA.

#### **Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- Patient must be untreated with gene therapy.

#### **Population criteria:**

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

## risdiplam 750 microgram/mL powder for oral liquid, 80 mL

14647X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	10890.56	Evrysdi [RO]

### ▪ RISDIPLAM

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood

#### **Population criteria:**

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood, **AND**
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19<sup>th</sup> birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

#### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

#### **Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Failure to gain weight appropriate for age,
- (vi) Any active denervation or chronic neurogenic changes found on electromyography,
- (vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,
- (2) which of the above (i to vii) (at least 1) were present during childhood,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

#### **risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

13632L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±3	7	..	*32574.33	Evrysdi [RO]

#### ▪ RISDIPLAM

**Note** Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. **Muscle & Nerve** 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. **PLoS ONE** 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. **American Journal of Respiratory and Critical Care Medicine** 166(1), pp 111-117

The National Health Foundation of Australia has 6MWT test standardised instructions and recording forms located at: <https://www.heartonline.org.au/resources/documents-and-links#exercise>

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. **Muscle & Nerve** 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. **Neurology** April (15 Supplement) P4.452

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicessaustralia.gov.au/HPOS](http://www.servicessaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

**Treatment criteria:**

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; OR
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19<sup>th</sup> birthday, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

13646F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±3	5	..	*32574.33	Evrysdi [RO]

▪ **RISDIPLAM**

**Note** The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicessaustralia.gov.au/HPOS](http://www.servicessaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

**Treatment criteria:**

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; OR
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19<sup>th</sup> birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

13659X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±3	5	..	*32574.33	Evrysdi [RO]

**■ RISDIPLAM****Note** The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.**Note** No increase in the maximum quantity or number of units may be authorised.**Note** No increase in the maximum number of repeats may be authorised.**Note** Special Pricing Arrangements apply.**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in a child

**Population criteria:**

- Patient must be of an age that is prior to their 19<sup>th</sup> birthday at the time of this authority application, **AND**
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday (SMA type IIIB/IIIC).

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**

- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Any active denervation or chronic neurogenic changes found on electromyography,
- (vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,
- (2) which of the above (i to vi) (at least 1) were present after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

13639W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±3	5	..	*32574.33	Evrysdi [RO]

■ **NERVOUS SYSTEM**

■ **ANTI-PARKINSON DRUGS**

**DOPAMINERGIC AGENTS**

*Dopa and dopa derivatives*

■ **LEVODOPA + CARBIDOPA**

**Note** Special Pricing Arrangements apply.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

**Authority required (STREAMLINED)**

**10161**

Advanced Parkinson disease

**Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

**levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

11910W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*5816.67	Duodopa [VE]

## ▪ LEVODOPA + CARBIDOPA

**Note** Special Pricing Arrangements apply.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

### **Authority required (STREAMLINED)**

**10363**

Advanced Parkinson disease

### **Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; OR
- Patient must require a total daily dose of more than 2000 mg of levodopa.

### **levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL**

9744W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*11584.67	Duodopa [VE]

### *Dopamine agonists*

## ▪ APOMORPHINE

### **Authority required (STREAMLINED)**

**10830**

Parkinson disease

### **Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

### **apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials**

11083H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	5	..	*7475.97	Apomine Solution for Infusion [IT]

## ▪ APOMORPHINE

### **Authority required (STREAMLINED)**

**11445**

Parkinson disease

### **Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

### **apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

9640J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*6078.27	Movapo [TD]

### **apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes**

10971K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8065.83	Movapo PFS [TD]

## ▪ APOMORPHINE

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

**Note** Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.

### **Authority required (STREAMLINED)**

**10830**

Parkinson disease

### **Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

### **apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges**

11688E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2636.67	<sup>a</sup> Apomine Intermittent [IT]

### **apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices**

11475Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2636.67	<sup>a</sup> Movapo Pen [TD]

■ PSYCHOLEPTICS

ANTIPSYCHOTICS

*Diazepines, oxazepines, thiazepines and oxepines*

■ CLOZAPINE

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

**Authority required (STREAMLINED)**

**9490**

Schizophrenia

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

**Clinical criteria:**

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

**clozapine 50 mg/mL oral liquid, 100 mL**

11415T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	149.07	Versacloz [PF]

■ CLOZAPINE

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS), Pfizer ClopineCentral or Juno Connected Clozitor.

**Authority required (STREAMLINED)**

**9490**

Schizophrenia

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

**Clinical criteria:**

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

**clozapine 50 mg/mL oral liquid, 100 mL**

9632Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	149.07	Clopine Suspension [PF]

**clozapine 100 mg tablet, 100**

6102E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*225.07	Clopine 100 [PF] Clozitor [JU]	Clozaril 100 [GO]

**clozapine 200 mg tablet, 100**

6418T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*441.47	Clopine 200 [PF]	Clozitor [JU]

**clozapine 25 mg tablet, 100**

6101D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*68.17	Clopine 25 [PF] Clozitor [JU]	Clozaril 25 [GO]

**clozapine 50 mg tablet, 100**

6417R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*124.09	Clopine 50 [PF]	Clozitor [JU]

HSD (Private)



## OTHER NERVOUS SYSTEM DRUGS

### OTHER NERVOUS SYSTEM DRUGS

#### *Other nervous system drugs*

#### ■ PATISIRAN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Hereditary transthyretin amyloidosis

Treatment Phase: Initial treatment

#### **Population criteria:**

- Patient must have either: (i) stage 1 polyneuropathy, (ii) stage 2 polyneuropathy.

#### **Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Clinical criteria:**

- The condition must be hereditary transthyretin amyloidosis confirmed by genetic testing, **AND**
- Patient must have a Polyneuropathy Disability (PND) score description of either I, II, IIIA, IIIB; OR
- Patient must have a Familial Amyloid Polyneuropathy (FAP) stage description of 1 or 2, **AND**
- Patient must not have previously undergone a liver transplant, **AND**
- Patient must not exhibit heart failure symptoms (defined as New York Heart Association NYHA class III or IV).

#### **Treatment criteria:**

- Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders, **AND**
- Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders).

PND scores in the context of this PBS restriction are:

Stage 0 - No symptoms;

Stage I - Sensory disturbances but preserved walking capability;

Stage II - Impaired walking capacity but able to walk without stick or crutches;

Stage IIIA - Walking with help of one stick or crutch;

Stage IIIB - Walking with help of two sticks or crutches;

Stage IV - Confined to wheelchair or bedridden.

FAP stage in the context of this PBS restriction are:

Stage 0 - No symptoms;

Stage 1 - Unimpaired ambulation;

Stage 2 - Assistance with ambulation required;

Stage 3 - Wheelchair-bound or bedridden.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

#### **Authority required**

Hereditary transthyretin amyloidosis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must continue to demonstrate clinical benefit, **AND**
- Patient must not be permanently bedridden; OR

- Patient must not be receiving end-of-life care. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- details of the proposed prescription; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### **Authority required**

Hereditary transthyretin amyloidosis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

### **Clinical criteria:**

- Patient must have received treatment with this drug for this condition prior to 1 August 2024, **AND**
- Patient must continue to demonstrate clinical benefit, **AND**
- Patient must not be permanently bedridden; OR
- Patient must not be receiving end-of-life care.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- details of the proposed prescription; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### **patisiran 10 mg/5 mL injection, 5 mL vial**

14296K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	7	..	*37398.45	Onpatro [WM]

## ■ RESPIRATORY SYSTEM

## ■ DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

### OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES

*Other systemic drugs for obstructive airway diseases*

## ■ BENRALIZUMAB

### **Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Balance of supply

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

#### **benralizumab 30 mg/mL injection, 1 mL pen device**

11999M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3194.12	Fasenra Pen [AP]

### ▪ BENRALIZUMAB

#### **Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or

(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

- (a) if applicable, details of maintenance oral corticosteroid dose; and
- (b) a completed Asthma Control Questionnaire (ACQ-5) score.

**benralizumab 30 mg/mL injection, 1 mL pen device**

11996J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	3194.12	Fasenra Pen [AP]

▪ **BENRALIZUMAB**

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omaliuzumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omaliuzumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omaliuzumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
  - (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.
- The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and
- (b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) the eosinophil count and date; and
- (e) Asthma Control Questionnaire (ACQ-5) score.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

### **Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- (b) details (date and duration of treatment) of prior biological medicine treatment; and
- (c) eosinophil count and date; and



(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and

(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

### benralizumab 30 mg/mL injection, 1 mL pen device

11997K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	3194.12	Fasenra Pen [AP]

## ▪ DUPILUMAB

### Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

#### (1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

#### (3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

#### (4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialed it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

#### (5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a

treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and, for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle. A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

- (a) if applicable, details of maintenance oral corticosteroid dose; and
- (b) a completed Asthma Control Questionnaire (ACQ-5) score.

#### **dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes**

12294C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1658.53	Dupilumab [SW]

#### **dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes**

12316F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1658.53	Dupilumab [SW]

### ■ DUPILUMAB

#### **Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

#### (1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

#### (3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

#### (4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on

the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have been receiving regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation, **AND**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

#### **Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

(i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; AND

(ii) treatment with oral corticosteroids as outlined in the clinical criteria.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and
- (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) Asthma Control Questionnaire (ACQ-5) score; and
- (e) if applicable, the eosinophil count and date; and
- (f) if applicable, the IgE result and date.

**Note** The Services Australia website ([www.servicessaustralia.gov.au](http://www.servicessaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have each of: (i) total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, (ii) past or current

evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**

- Patient must have received regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- (b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and
- (c) if applicable, the eosinophil count and date; and
- (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- (e) if applicable, the IgE result and date; and
- (f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

**dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes**

12310X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	8	..	1658.53	Dupixent [SW]

▪ **DUPILUMAB**

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a

treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialed it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omaliuzumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omaliuzumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omaliuzumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or [MedInfo.Australia@sanofi.com](mailto:MedInfo.Australia@sanofi.com)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:



- (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and
- (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) Asthma Control Questionnaire (ACQ-5) score; and
- (e) if applicable, the eosinophil count and date; and
- (f) if applicable, the IgE result and date.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

#### **Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- (b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and
- (c) if applicable, the eosinophil count and date; and
- (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- (e) if applicable, the IgE result and date; and
- (f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

## **dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes**

12313C	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	8	..	1658.53	Dupilumab [SW]

## ■ **MEPOLIZUMAB**

### **Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

#### (1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

#### (3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

#### (4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Balance of supply

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

#### **mepolizumab 100 mg/mL injection, 1 mL pen device**

12043W	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1604.77	Nucala [GK]

### ▪ MEPOLIZUMAB

#### **Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological

medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below]. All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

- (a) if applicable, details of maintenance oral corticosteroid dose; and
- (b) a completed Asthma Control Questionnaire (ACQ-5) score.

#### mepolizumab 100 mg/mL injection, 1 mL pen device

12052H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1604.77	Nucala [GK]

### ■ MEPOLIZUMAB

#### Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to

ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omaliuzumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omaliuzumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omaliuzumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**

- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and
- (b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) the eosinophil count and date; and
- (e) Asthma Control Questionnaire (ACQ-5) score.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- (b) details (date and duration of treatment) of prior biological medicine treatment; and
- (c) eosinophil count and date; and
- (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

**mepolizumab 100 mg/mL injection, 1 mL pen device**

12051G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	1604.77	Nucala [GK]

▪ **MEPOLIZUMAB**

**Note** The length of a break in therapy is measured from the date that the relevant PBS-subsidised medicine listed for this PBS indication is ceased during the most recent treatment cycle, until the date of the subsequent application for treatment under a new treatment cycle.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.



**Clinical criteria:**

- Patient must have a diagnosis of CRSwNP confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan, with the results documented in the patient's medical records; OR
- Patient must have a diagnosis of CRSwNP from at least two physicians of the above mentioned prescriber types, **AND**
- Patient must have undergone surgery for the removal of nasal polyps; OR
- Patient must have the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery, **AND**
- Patient must have, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10), **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have had a 12 month break in PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma, **AND**
- Patient must have failed to achieve adequate control with optimised nasal polyp therapy which has been documented, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months.

**Population criteria:**

- Patient must be at least 18 years of age.

Optimised nasal polyp therapy includes:

- (a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated
- (b) if required, nasal irrigation with saline

Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form,
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),
- (c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,
- (d) details (date and treatment) of nasal polyp surgery; or
- (e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,
- (f) the eosinophil count and date,
- (g) two of the following, measured within the past 12 months: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have both demonstrated and sustained an adequate response to this drug, defined as having at least one of: (i) an improvement in bilateral endoscopic nasal polyp score of at least 1.0 compared to the baseline level provided with the initial authority application, (ii) an improvement in nasal obstruction visual analogue scale (VAS) score of at least 3.0 compared to the baseline level provided with the initial authority application, (iii) an improvement in overall symptom VAS score of at least 2.5 compared to the baseline level provided with the initial authority application.

**Population criteria:**

- Patient must be at least 18 years of age.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**mepolizumab 100 mg/mL injection, 1 mL pen device**

13242Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1604.77	Nucala [GK]

**■ OMALIZUMAB****Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
  - (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
  - (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
- All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omaliuzumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab

(see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Balance of supply

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

#### **omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

11826K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	120.57	Xolair [NV]

#### **omalizumab 150 mg/mL injection, 1 mL syringe**

11825J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	232.47	Xolair [NV]

### ■ OMALIZUMAB

#### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

Services Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Services Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Balance of supply in a patient aged 6 to 12 years

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction.

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

11958J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	120.57	Xolair [NV]

**omalizumab 150 mg/mL injection, 1 mL syringe**

11932B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	232.47	Xolair [NV]

**■ OMALIZUMAB****Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

**(1) Initial treatment:**

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

**(2) Continuing treatment:**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

**(3) Baseline measurements to determine response:**

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

- (a) Asthma Control Questionnaire (ACQ-5) score; and
- (b) If applicable, maintenance oral corticosteroid dose; and
- (c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

## omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11840E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	120.57	Xolair [NV]

## omalizumab 150 mg/mL injection, 1 mL syringe

11864K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	232.47	Xolair [NV]

## ■ OMALIZUMAB

### Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

Services Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Services Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to omalizumab treatment is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR
- (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR
- (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.

Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

- (a) If applicable, the baseline and maintenance oral corticosteroid dose; and
- (b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or
- (c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and
- (d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

#### omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11952C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	120.57	Xolair [NV]

#### omalizumab 150 mg/mL injection, 1 mL syringe

11953D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	232.47	Xolair [NV]

## ■ OMALIZUMAB

### Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new

treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below]. All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater



than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR

- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and
- (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) the IgE result and date; and
- (e) Asthma Control Questionnaire (ACQ-5) score.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au));

the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

## **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

## **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

## **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

## **Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- details (date and duration of treatment) of prior biological medicine treatment; and
- the IgE results and date; and
- if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

## **omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

10110D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	120.57	Xolair [NV]

## **omalizumab 150 mg/mL injection, 1 mL syringe**

10122R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	232.47	Xolair [NV]

## **■ OMALIZUMAB**

### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

Services Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Services Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos).  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

#### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either: a (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to less than 12 years.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; AND

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
- (b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (c) the IgE result and date; and
- (d) Asthma Control Questionnaire (ACQ-5) score; or
- (e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

10956P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	120.57	Xolair [NV]

**omalizumab 150 mg/mL injection, 1 mL syringe**

10968G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	232.47	Xolair [NV]

## COUGH AND COLD PREPARATIONS

### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

#### Mucolytics

#### ▪ DORNASE ALFA

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required (STREAMLINED)**

**9624**

Cystic fibrosis

**Population criteria:**

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required (STREAMLINED)**

**9591**

Cystic fibrosis

**Clinical criteria:**

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR
- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

**Population criteria:**

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required (STREAMLINED)**

**9592**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules**

6120D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1539.65	Pulmozyme [RO]

■ **MANNITOL**

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required (STREAMLINED)**

**9527**

Cystic fibrosis

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

**Population criteria:**

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND  
 (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required (STREAMLINED)**

**9593**

Cystic fibrosis

**Clinical criteria:**

- The treatment must be in combination with dornase alfa, **AND**
- Patient must be inadequately responsive to dornase alfa, **AND**
- Patient must have trialled hypertonic saline for this condition.

**Population criteria:**

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND  
 (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**mannitol 40 mg powder for inhalation, 280 capsules**

2008Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1837.87	Bronchitol [HT]

**OTHER RESPIRATORY SYSTEM PRODUCTS**  
 OTHER RESPIRATORY SYSTEM PRODUCTS  
*Other respiratory system products*

**▪ ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**

**Note** For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elexacaftor/ tezacaftor/ ivacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

**Population criteria:**

- Patient must be at least 6 years of age.  
This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

#### **Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

#### **Population criteria:**

- Patient must be at least 6 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

### **elixacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84**

12938Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Trikafta [VR]

### ▪ **ELEXACAFITOR + TEZACAFITOR + IVACAFTOR (&) IVACAFTOR**

**Note** For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elixacaftor/ tezacaftor/ ivacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

#### **Population criteria:**

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84**

13266F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Trikafta [VR]

**▪ ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**

**Note** For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elexacaftor/ tezacaftor/ ivacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

**Population criteria:**

- Patient must be 2 to 5 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and

HSD (Private)



(3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and

(4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 2 to 5 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**elexacftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (& ivacaftor 75 mg granules [28], 56**

14280N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Trikafta [VR]

**elexacftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (& ivacaftor 59.5 mg granules [28], 56**

14279M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Trikafta [VR]

■ **IVACFTOR**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (non-gating mutations)

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 4 months or older.

For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA approved Product Information. Quote each of the: (i) the specific mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment (non-gating mutations)

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**ivacaftor 150 mg tablet, 56**

14169R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Kalydeco [VR]

**ivacaftor 50 mg granules, 56 sachets**

14158E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Kalydeco [VR]

**ivacaftor 75 mg granules, 56 sachets**

14157D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Kalydeco [VR]

**ivacaftor 25 mg granules, 56 sachets**

14147N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Kalydeco [VR]

**■ IVACAFTOR**

- Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (gating mutations)

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (i) the specific CFTR mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

- Note** For the purposes of this restriction, the list of gating mutations are: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment (gating mutations)

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan,

indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**ivacaftor 150 mg tablet, 56**

10175M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Kalydeco [VR]

**ivacaftor 50 mg granules, 56 sachets**

11097C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Kalydeco [VR]

**ivacaftor 75 mg granules, 56 sachets**

11109Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Kalydeco [VR]

**ivacaftor 25 mg granules, 56 sachets**

14165M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20354.92	Kalydeco [VR]

▪ **LUMACAFTOR + IVACAFTOR**

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

**Population criteria:**

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

**Population criteria:**

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**lumacaftor 200 mg + ivacaftor 125 mg tablet, 112**

11463H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	16970.55	Orkambi [VR]

▪ **LUMACAFTOR + IVACAFTOR**

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

**Population criteria:**

- Patient must be aged between 6 and 11 years inclusive.  
This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

### **Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

### **Population criteria:**

- Patient must be aged between 6 and 11 years inclusive.  
This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

## **lumacaftor 100 mg + ivacaftor 125 mg tablet, 112**

11464J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	16970.55	Orkambi [VR]

## ▪ LUMACAFTOR + IVACAFTOR

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment

### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

### **Clinical criteria:**

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

### **Population criteria:**

- Patient must be 1 year of age or older.  
This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

#### **Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

#### **Population criteria:**

- Patient must be 1 year of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

#### **lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets**

11841F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	5	..	16970.55	Orkambi [VR]

#### **lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets**

11848N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	5	..	16970.55	Orkambi [VR]

#### **lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets**

13795C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	5	..	16970.55	Orkambi [VR]

#### **▪ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**

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

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

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**

- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

**Population criteria:**

- Patient must be 12 years of age or older.

For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient having at least one RF mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient ; and
- (4) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Authority required**

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56**

11833T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19001.17	Symdeko [VR]

HSD (Private)



## ▪ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

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

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

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Special Pricing Arrangements apply.

### **Authority required**

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

#### **Population criteria:**

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

### **Authority required**

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

#### **Population criteria:**

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56**

11834W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19001.17	Symdeko [VR]

■ **VARIOUS**

■ **ALL OTHER THERAPEUTIC PRODUCTS**

**ALL OTHER THERAPEUTIC PRODUCTS**

*Iron chelating agents*

■ **DEFERASIROX**

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

**deferasirox 180 mg tablet, 30**

11546Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*189.75	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 360 mg tablet, 30**

11496C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*370.83	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 90 mg tablet, 30**

11545P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*99.75	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

■ **DEFERASIROX**

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**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

**deferasirox 125 mg dispersible tablet, 28**

6499C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*626.13	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 250 mg dispersible tablet, 28**

6500D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*860.13	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 500 mg dispersible tablet, 28**

9600G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*2423.37	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**▪ DEFERASIROX****Authority required (STREAMLINED)****9302**

Chronic iron overload

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

**Authority required (STREAMLINED)****9222**

Chronic iron overload

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

**Authority required (STREAMLINED)****9258**

Chronic iron overload

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

**Note** Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/mL.

**deferasirox 125 mg dispersible tablet, 28**

11236J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*626.13	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 250 mg dispersible tablet, 28**

11238L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*860.13	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 500 mg dispersible tablet, 28**

11243R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*2423.37	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 180 mg tablet, 30**

11510T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*189.75	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 360 mg tablet, 30**

11547R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*370.83	<sup>a</sup> Deferasirox ARX [XT]	<sup>a</sup> Deferasirox Sandoz [SZ]

<sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Eferas [AF]  
<sup>a</sup> Jadenu [NM] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 90 mg tablet, 30**

11548T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*99.75	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

▪ **DEFERASIROX**

**Note** A patient's median life expectancy is determined by the severity of their underlying disease.

**Note** Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

**Note** Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

**deferasirox 180 mg tablet, 30**

11557G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*189.75	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 360 mg tablet, 30**

11511W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*370.83	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 90 mg tablet, 30**

11558H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*99.75	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

▪ **DEFERASIROX**

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**Note** A patient's median life expectancy is determined by the severity of their underlying disease.

**Note** Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

**Note** Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

**deferasirox 125 mg dispersible tablet, 28**

11241P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*626.13	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 250 mg dispersible tablet, 28**

11244T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*860.13	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 500 mg dispersible tablet, 28**

11232E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*2423.37	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**▪ DEFERIPRONE****Authority required (STREAMLINED)****9286**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

**Authority required (STREAMLINED)****9228**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

**deferiprone 100 mg/mL oral liquid, 250 mL**

9638G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	5	..	*1010.27	Ferriprox [EU]

**deferiprone 500 mg tablet, 100**

6416Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*1204.35	Ferriprox [EU]

**▪ DEFERIPRONE****Authority required (STREAMLINED)****9623**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

**Authority required (STREAMLINED)****9590**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

**deferiprone 1 g tablet, 50**

11724C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*2360.07	Ferriprox [EU]

**▪ DESFERRIOXAMINE****Authority required (STREAMLINED)****9696**

Disorders of erythropoiesis

**Clinical criteria:**

- The condition must be associated with treatment-related chronic iron overload.

**desferrioxamine mesilate 2 g injection, 1 vial**

6270B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	60	5	..	*2663.67	DBL Desferrioxamine Mesilate [PF]

**desferrioxamine mesilate 500 mg injection, 10 vials**

6113R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	40	5	..	*5603.87	DBL Desferrioxamine Mesilate [PF]

***Drugs for treatment of hyperkalemia and hyperphosphatemia*****▪ LANTHANUM****Authority required (STREAMLINED)****9762**

Hyperphosphataemia  
Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**lanthanum 500 mg chewable tablet, 2 x 45**

9635D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*352.71	Fosrenol [TK]

**lanthanum 750 mg chewable tablet, 6 x 15**

9636E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*528.17	Fosrenol [TK]

**lanthanum 1 g chewable tablet, 6 x 15**

9637F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*593.51	Fosrenol [TK]

▪ **SEVELAMER**

**Note** Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

**Authority required (STREAMLINED)**

**9762**

Hyperphosphataemia  
Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer carbonate 800 mg tablet, 180**

11838C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*338.99	<sup>a</sup> ARX-SEVELAMER [XT] <sup>a</sup> Sevelamer Lupin [GQ]	<sup>a</sup> Sevelamer Apotex [TX]

**sevelamer hydrochloride 800 mg tablet, 180**

9620H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*338.99	<sup>a</sup> Renagel [GZ]

▪ **SUCROFERRIC OXYHYDROXIDE**

**Authority required (STREAMLINED)**

**9762**

Hyperphosphataemia  
Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90**

10230K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*715.87	Velphoro [VL]

*Other therapeutic products*

## ▪ DIFELIKEFALIN

- Note** See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):  
Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. *J Patient Rep Outcomes*. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z  
The WI-NRS scale is available as downloadable document in the supplementary information section at:  
[www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/)
- Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.

### **Authority required**

Moderate to severe pruritus (itching) associated with chronic kidney disease  
Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must be on optimised haemodialysis, **AND**
- Patient must be on haemodialysis for at least 3 months, **AND**
- The condition must be confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus, **AND**
- Patient must have experienced itch that persists for at least 6 weeks despite best supportive care, **AND**
- Patient must have a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) baseline score of more than 4, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

### **Treatment criteria:**

- Must be treated by a nephrologist.

### **Population criteria:**

- Patient must be at least 18 years of age.

Prescriber must exclude any other causes of pruritus which include any of the following:

- drug/dialysis related (e.g., opioid-related pruritus);
- drug hypersensitivity or adverse effect; contact dermatitis; allergy;
- differential diagnoses (e.g., xerosis; infestations; iron deficiency; liver disease; polycythaemia vera/leukemia/lymphoma; hypothyroidism; uncontrolled diabetes).

Best supportive care for patients with chronic kidney disease-associated pruritus is not limited to but includes:

- optimisation of dialysis;
- skin hydration and nutrition (with the use of moisturiser, emollients, barrier creams or oils);
- patient education on the importance of avoiding or minimising scratching.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 2 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

### **difelikefalin 50 microgram/mL injection, 12 x 1 mL vials**

14110P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	570.27	Korsuva [CS]

## ▪ DIFELIKEFALIN

- Note** See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):  
Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. *J Patient Rep Outcomes*. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z  
The WI-NRS scale is available as downloadable document in the supplementary information section at:  
[www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/)
- Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.

### **Authority required**

Moderate to severe pruritus (itching) associated with chronic kidney disease  
Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

### **Treatment criteria:**

- Must be treated by a nephrologist; OR

- Must be treated by a medical practitioner in consultation with a nephrologist. Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records. At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

**Authority required**

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS-subsidised supply was commenced, the patient: (i) was on optimised haemodialysis; (ii) was on haemodialysis for at least 3 months; (iii) had a condition confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus; (iv) had experienced itch that persists for at least 6 weeks despite best supportive care; (v) had a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) of more than 4 at baseline, **AND**
- Patient must have demonstrated an adequate response to the most recent non-PBS-subsidised treatment with this drug for this condition, including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

**Treatment criteria:**

- Must be treated by a nephrologist.

**Population criteria:**

- Patient must be at least 18 years of age.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

**Note** A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**difelikefalin 50 microgram/mL injection, 12 x 1 mL vials**

14106K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	570.27	Korsuva [CS]

HSD (Private)



# Highly Specialised Drugs Program (Public Hospital)

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## ALIMENTARY TRACT AND METABOLISM

### OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

#### OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS

*Various alimentary tract and metabolism products*

#### ▪ TEDUGLUTIDE

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

##### **Authority required**

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment - balance of supply

##### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

##### **Clinical criteria:**

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have received insufficient therapy with this drug under the initial treatment restriction to complete the maximum duration of 12 months of initial treatment, **AND**
- The treatment must provide no more than the balance of up to 12 months of treatment.

#### **teduglutide 5 mg injection [28 vials] (& inert substance diluent [28 x 0.5 mL syringes], 1 pack**

11808L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	19710.60	Revestive [TK]

#### ▪ TEDUGLUTIDE

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

##### **Authority required**

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Continuing treatment

##### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

##### **Clinical criteria:**

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have a reduction in parenteral support frequency of at least one day per week compared to the mean number of days per week at baseline; OR
- Patient must have, as a patient yet to turn 18 years of age, a reduction in the mean weekly parenteral support volume of at least 20% (mL per kg of body weight) relative to baseline; OR
- The treatment must be resuming after a break in therapy, but before the break in therapy occurred, a reduction in parenteral support relative to baseline had been occurring to an extent as stated as above.

Refer to the measurement(s) stated in the Initial treatment authority application for the baseline dependence on parenteral support. Determine the current mean use per week of parental support in days (for a patient of any age) and/or the mean volume per week in mL per kg (for a patient yet to turn 18 years of age). State these values in this authority application.

The current mean number of days of parenteral support is calculated as the mean number of days in which any parenteral support is required (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.

The current mean weekly parenteral support volume is calculated as the mean mL per kg of body weight of parenteral support (parenteral nutrition with or without IV fluids) per week to meet caloric, fluid or electrolyte needs over a 4 week timeframe that best represents the average of the preceding treatment period.

From 1 September 2021

Where the mean weekly volume of parenteral support in terms of mL per kg of body weight for 4 consecutive weeks has not been stated in an Initial treatment authority application for a patient yet to turn 18 years of age, provide in this authority application both:

- (i) a known or estimated retrospective baseline value that would have applied to the patient immediately before commencing treatment with this drug, and
- (ii) the current value (observed over a 4 week timeframe)

Provide these values for a child only where mean weekly volume is to be used as an alternative response assessment to mean days of parenteral support per week. Otherwise, continue to use mean days per week.

Where treatment is resuming after a break in treatment with this drug, state parenteral support days/volume values as occurring prior to the break instead of current values.

A patient who has turned 18 years of age since their last authority application may be assessed for response using either the mean number of days of parenteral support or mean volume of parenteral support. Any subsequent authority application after this application must be assessed using the mean number of days of parenteral support.

Patients who do not meet the clinical criteria with respect to demonstrating the minimum reduction in parenteral support must permanently discontinue PBS subsidy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### teduglutide 5 mg injection [28 vials] (& inert substance diluent [28 x 0.5 mL syringes], 1 pack

11794R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	19710.60	Revestive [TK]

#### ▪ TEDUGLUTIDE

**Note** A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Type III Short bowel syndrome with intestinal failure

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a specialist within a multidisciplinary intestinal rehabilitation unit.

#### **Clinical criteria:**

- Patient must have short bowel syndrome with intestinal failure following major surgery, **AND**
- Patient must have a history of dependence on parenteral support for at least 12 months, **AND**
- Patient must have received a stable parenteral support regimen for at least 3 days per week in the previous 4 weeks, **AND**
- Patient must not have active gastrointestinal malignancy or history of gastrointestinal malignancy within the last 5 years, **AND**
- The treatment must not exceed 12 months under this restriction, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition.

Provide a baseline value in this authority application of the amount of parenteral support per week, expressed as either:

- (i) for a patient of any age, the mean number of days of parenteral support per week
- (ii) for a patient yet to turn 18 years of age, the mean volume of parenteral support per week in mL per kg.

Determine the mean over any given 4 week period prior to this authority application. For a patient yet to turn 18 years of age, both (i) and (ii) may be supplied, but provide at least (i).

Assessment of treatment response/non-response in the 'Continuing treatment' authority application will be compared against the baseline value(s) submitted in this application.

A stable parenteral support regimen is defined as a minimum of 3 days of parenteral support (parenteral nutrition with or without IV fluids) per week for 4 consecutive weeks to meet caloric, fluid or electrolyte needs.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**teduglutide 5 mg injection [28 vials] (&) inert substance diluent [28 x 0.5 mL syringes], 1 pack**

11793Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	19710.60	Revestive [TK]

## ■ BLOOD AND BLOOD FORMING ORGANS

### ■ ANTIHEMORRHAGICS

#### VITAMIN K AND OTHER HEMOSTATICS

*Other systemic hemostatics*

### ■ AVATROMBOPAG

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

**Note** Special Pricing Arrangements apply.

#### Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

A maximum of 24 weeks of treatment with this drug will be authorised under this criterion.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

#### Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

#### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
  - Patient must have changed treatment from either romiplostim or eltrombopag to this drug under the Balance of Supply/Change of Therapy restriction and demonstrated a sustained response; OR
  - Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

## BLOOD AND BLOOD FORMING ORGANS

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
  - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
  - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
  - Patient must be changing therapy from romiplostim or eltrombopag to this drug for this condition, **AND**
  - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with romiplostim or eltrombopag may change to avatrombopag under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **avatrombopag 20 mg tablet, 30**

13313Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2601.06	Doptelet [ZO]

### ▪ **ELTROMBOPAG**

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

### **Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
  - Patient must have demonstrated a response to PBS-subsidised treatment with this drug.
- Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than  $50 \times 10^9/L$ , haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than  $1 \times 10^9/L$  for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

### **eltrombopag 25 mg tablet, 28**

14120E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*3684.36	Revolade [NV]

## ▪ ELTROMBOPAG

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Severe aplastic anaemia

Treatment Phase: Initial treatment - Second line treatment

### **Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
  - Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR
  - Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
  - Patient must not receive more than 16 weeks of treatment under this restriction.
- The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

### eltrombopag 25 mg tablet, 28

14144K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	3	..	*3684.36	Revolade [NV]

## ▪ ELTROMBOPAG

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

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required

Severe aplastic anaemia

Treatment Phase: Continuing treatment - Second line treatment

### **Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial treatment restriction, **AND**
- Patient must have demonstrated a response to PBS-subsidised treatment with this drug.  
Platelet, haemoglobin and neutrophil counts must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

Once platelet count is greater than  $50 \times 10^9/L$ , haemoglobin is greater than 100 g/L in the absence of red blood cell (RBC) transfusion, and absolute neutrophil (ANC) is greater than  $1 \times 10^9/L$  for more than 8 weeks, the dose of eltrombopag should be reduced as per the Product Information.

For the purposes of this restriction, a response is defined as no longer meeting the criteria for severe aplastic anaemia.

### eltrombopag 50 mg tablet, 28

14112R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*7368.72	Revolade [NV]

## ▪ ELTROMBOPAG

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Severe aplastic anaemia  
 Treatment Phase: Initial treatment - Second line treatment

**Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have achieved an adequate response to prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin; OR
- Patient must have relapsed following prior immunosuppressive therapy including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

The authority application must be made via the online PBS Authorities (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) prior immunosuppressive therapy, including dates of treatment.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**eltrombopag 50 mg tablet, 28**

14121F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	3	..	*7368.72	Revolade [NV]

▪ **ELTROMBOPAG**

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Severe aplastic anaemia  
 Treatment Phase: First line treatment

**Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Severe aplastic anaemia  
 Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - First line treatment

**Clinical criteria:**



- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A patient may qualify for PBS-subsidised treatment under this restriction once only.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**eltrombopag 25 mg tablet, 28**

14128N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*3684.36	Revolade [NV]

▪ **ELTROMBOPAG**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe aplastic anaemia

Treatment Phase: First line treatment

**Clinical criteria:**

- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Severe aplastic anaemia

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements - First line treatment

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- The condition must be severe aplastic anaemia, **AND**
- Patient must not have received treatment with immunosuppressive therapy for this condition prior to initiating non-PBS-subsidised treatment, **AND**
- The treatment must be administered in combination with standard immunosuppressive therapy, including anti-thymocyte antibody and ciclosporin, **AND**
- Patient must be considered ineligible for haemopoietic stem cell transplant, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction in a lifetime.

If the application is submitted through HPOS form upload or mail, it must include:

- A completed authority prescription form; and
- A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

A patient may qualify for PBS-subsidised treatment under this restriction once only.

## BLOOD AND BLOOD FORMING ORGANS

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

### eltrombopag 50 mg tablet, 28

14131R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*7368.72	Revolade [NV]

#### ■ ELTROMBOPAG

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

**Note** Special Pricing Arrangements apply.

##### Authority required

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

##### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

##### Authority required

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

##### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

##### Authority required

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
  - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
  - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
  - Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
  - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**eltrombopag 25 mg tablet, 28**

5825N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1228.12	Revolade [NV]

▪ **ELTROMBOPAG**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
  - Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;
- (a) a platelet count of less than or equal to 20,000 million per L; OR
- (b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

## BLOOD AND BLOOD FORMING ORGANS

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

### **Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
  - Patient must have changed treatment from either romiplostim or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
  - Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
  - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

### **Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
  - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
  - Patient must be changing therapy from romiplostim or avatrombopag to this drug for this condition, **AND**
  - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with romiplostim or avatrombopag may change to eltrombopag under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **eltrombopag 50 mg tablet, 28**

5826P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2456.24	Revolade [NV]

### ▪ ROMIPILOSTIM

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

### **Authority required**

Severe thrombocytopenia

Treatment Phase: Initial treatment - New patient

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, corticosteroid therapy, **AND**
- Patient must have failed to achieve an adequate response to, or be intolerant to, immunoglobulin therapy, **AND**
- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

The following criteria indicate failure to achieve an adequate response to corticosteroid and/or immunoglobulin therapy and must be demonstrated at the time of initial application;

(a) a platelet count of less than or equal to 20,000 million per L; OR

(b) a platelet count of 20,000 million to 30,000 million per L, where the patient is experiencing significant bleeding or has a history of significant bleeding in this platelet range.

The medical practitioner should request 1 vial of the appropriate strength, to titrate therapy based on the weight of the patient. A maximum of 5 repeats will be authorised.

Once a patient's dose has been stable for a period of 4 weeks, authority approvals for sufficient vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) for up to 4 weeks of treatment, may be requested under the Balance of supply or change of therapy restriction. The total period of treatment authorised under this restriction must not exceed 24 weeks.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details of a platelet count supporting the diagnosis of ITP.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe thrombocytopenia

Treatment Phase: First Continuing treatment or Re-initiation of interrupted continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
- Patient must have demonstrated a sustained platelet response to PBS-subsidised treatment with this drug for this condition under the Initial treatment restriction if the patient has not had a treatment break, confirmed through a pathology report from an Approved Pathology Authority; OR
- Patient must have changed treatment from either eltrombopag or avatrombopag to this drug under the Balance of Supply/Change of therapy restriction and demonstrated a sustained response; OR
- Patient must have demonstrated a sustained platelet response to the most recent PBS-subsidised treatment with this drug for this condition prior to interrupted treatment, confirmed through a pathology report from an Approved Pathology Authority, **AND**

- The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.

For the purposes of this restriction, a sustained response is defined as the patient having the ability to maintain a platelet count sufficient to prevent clinically significant bleeding based on clinical assessment.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

The platelet count must be conducted no later than 4 weeks from the date of completion of the most recent PBS-subsidised course of treatment with this drug and must be documented in the patient's medical records.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe thrombocytopenia

Treatment Phase: Second or Subsequent Continuing treatment

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - Patient must have previously received PBS-subsidised treatment with this drug for this condition under first continuing or re-initiation of interrupted continuing treatment restriction, **AND**
  - Patient must have demonstrated a continuing response to PBS-subsidised treatment with this drug, **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition.
- The platelet count must be no more than 4 weeks old at the time of application and must be documented in the patient's medical records.

The medical practitioner should request sufficient number of vials of appropriate strength based on the weight of the patient and dose (microgram/kg/week) to provide 4 weeks of treatment. Up to a maximum of 5 repeats may be authorised.

Authority approval will not be given for doses higher than 10 micrograms/kg/week

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe thrombocytopenia

Treatment Phase: Balance of supply or change of therapy

**Clinical criteria:**

- The condition must be severe chronic immune (idiopathic) thrombocytopenic purpura (ITP), **AND**
  - The treatment must be the sole PBS-subsidised thrombopoietin receptor agonist (TRA) for this condition, **AND**
  - Patient must have received insufficient therapy with this drug for this condition under the Initial treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the First Continuing treatment or Re-initiation of interrupted continuing treatment restriction; OR
  - Patient must have received insufficient therapy with this drug for this condition under the Second or Subsequent Continuing treatment restriction; OR
  - Patient must be changing therapy from eltrombopag or avatrombopag to this drug for this condition, **AND**
  - The treatment must provide no more than the balance of up to 24 weeks treatment under this restriction.
- Patients receiving treatment with eltrombopag or avatrombopag may change to romiplostim under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**romiplostim 250 microgram injection, 1 vial**

9696H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	494.12	Nplate [AN]

**romiplostim 500 microgram injection, 1 vial**

9698K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	988.24	Nplate [AN]

**ANTIANEMIC PREPARATIONS**

**OTHER ANTIANEMIC PREPARATIONS**

*Other antianemic preparations*

**DARBEPOETIN ALFA**

**Authority required (STREAMLINED)**

**6294**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**darbepoetin alfa 10 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

5637Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*224.36	Aranesp [AN]

**darbepoetin alfa 100 microgram/0.5 mL injection, 0.5 mL pen device**

5649H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1651.12	Aranesp SureClick [AN]

**darbepoetin alfa 100 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

5651K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1651.16	Aranesp [AN]

**darbepoetin alfa 150 microgram/0.3 mL injection, 0.3 mL pen device**

5650J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*2460.16	Aranesp SureClick [AN]

**darbepoetin alfa 150 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

5643B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2460.18	Aranesp [AN]

**darbepoetin alfa 20 microgram/0.5 mL injection, 0.5 mL pen device**

5645D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*422.56	Aranesp SureClick [AN]

**darbepoetin alfa 20 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

5638R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*422.54	Aranesp [AN]

**darbepoetin alfa 30 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

5639T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*578.08	Aranesp [AN]

**darbepoetin alfa 40 microgram/0.4 mL injection, 0.4 mL pen device**

5646E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*701.60	Aranesp SureClick [AN]

**darbepoetin alfa 40 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

5640W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*701.66	Aranesp [AN]

**darbepoetin alfa 50 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

5641X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*867.48	Aranesp [AN]

**darbepoetin alfa 60 microgram/0.3 mL injection, 0.3 mL pen device**

5647F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1018.64	Aranesp SureClick [AN]

**darbepoetin alfa 60 microgram/0.3 mL injection, 4 x 0.3 mL syringes**

5642Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1018.64	Aranesp [AN]

**darbepoetin alfa 80 microgram/0.4 mL injection, 0.4 mL pen device**

5648G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*1340.88	Aranesp SureClick [AN]

**darbepoetin alfa 80 microgram/0.4 mL injection, 4 x 0.4 mL syringes**

5644C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1340.82	Aranesp [AN]

▪ **EPOETIN ALFA**

**Authority required (STREAMLINED)**

**6294**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin alfa 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

5714R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*175.98	Epex 1000 [JC]

**epoetin alfa 10 000 units/mL injection, 6 x 1 mL syringes**

5722E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1241.44	Epex 10000 [JC]

## BLOOD AND BLOOD FORMING ORGANS

### epoetin alfa 2000 units/0.5 mL injection, 6 x 0.5 mL syringes

5719B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*325.64	Eprex 2000 [JC]

### epoetin alfa 20 000 units/0.5 mL injection, 6 x 0.5 mL syringes

5713Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2442.22	Eprex 20,000 [JC]

### epoetin alfa 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

5720C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*420.20	Eprex 3000 [JC]

### epoetin alfa 4000 units/0.4 mL injection, 6 x 0.4 mL syringes

5721D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*535.14	Eprex 4000 [JC]

### epoetin alfa 40 000 units/mL injection, 1 mL syringe

5718Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*790.12	Eprex 40,000 [JC]

### epoetin alfa 5000 units/0.5 mL injection, 6 x 0.5 mL syringes

5715T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*666.22	Eprex 5000 [JC]

### epoetin alfa 6000 units/0.6 mL injection, 6 x 0.6 mL syringes

5716W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*790.84	Eprex 6000 [JC]

### epoetin alfa 8000 units/0.8 mL injection, 6 x 0.8 mL syringes

5717X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1025.72	Eprex 8000 [JC]

## ■ EPOETIN BETA

### Authority required (STREAMLINED)

**6294**

Anaemia associated with intrinsic renal disease

#### Clinical criteria:

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

### epoetin beta 10 000 units/0.6 mL injection, 6 x 0.6 mL syringes

5729M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1241.36	NeoRecormon [RO]

### epoetin beta 2000 units/0.3 mL injection, 6 x 0.3 mL syringes

5724G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*325.60	NeoRecormon [RO]

### epoetin beta 3000 units/0.3 mL injection, 6 x 0.3 mL syringes

5725H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*420.18	NeoRecormon [RO]

### epoetin beta 4000 units/0.3 mL injection, 6 x 0.3 mL syringes

5726J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*535.10	NeoRecormon [RO]

### epoetin beta 5000 units/0.3 mL injection, 6 x 0.3 mL syringes

5727K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*666.18	NeoRecormon [RO]

### epoetin beta 6000 units/0.3 mL injection, 6 x 0.3 mL syringes

5728L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*790.78	NeoRecormon [RO]

## ■ EPOETIN LAMBDA

### Authority required (STREAMLINED)



**6294**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**epoetin lambda 1000 units/0.5 mL injection, 6 x 0.5 mL syringes**

9668W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*226.24	Novicrit [SZ]

**epoetin lambda 10 000 units/mL injection, 6 x 1 mL syringes**

9596C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1595.96	Novicrit [SZ]

**epoetin lambda 2000 units/mL injection, 6 x 1 mL syringes**

9669X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*418.60	Novicrit [SZ]

**epoetin lambda 3000 units/0.3 mL injection, 6 x 0.3 mL syringes**

9670Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*540.20	Novicrit [SZ]

**epoetin lambda 4000 units/0.4 mL injection, 6 x 0.4 mL syringes**

9587N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*687.94	Novicrit [SZ]

**epoetin lambda 5000 units/0.5 mL injection, 6 x 0.5 mL syringes**

9589Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*856.46	Novicrit [SZ]

**epoetin lambda 6000 units/0.6 mL injection, 6 x 0.6 mL syringes**

9591T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1016.66	Novicrit [SZ]

**epoetin lambda 8000 units/0.8 mL injection, 6 x 0.8 mL syringes**

9594Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1318.60	Novicrit [SZ]

▪ **METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA**

**Authority required (STREAMLINED)**

**6294**

Anaemia associated with intrinsic renal disease

**Clinical criteria:**

- Patient must require transfusion, **AND**
- Patient must have a haemoglobin level of less than 100 g per L, **AND**
- Patient must have intrinsic renal disease, as assessed by a nephrologist.

**methoxy polyethylene glycol-epoetin beta 30 microgram/0.3 mL injection, 0.3 mL syringe**

5794Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*221.00	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 50 microgram/0.3 mL injection, 0.3 mL syringe**

5795B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*368.34	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 75 microgram/0.3 mL injection, 0.3 mL syringe**

5796C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*536.36	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 100 microgram/0.3 mL injection, 0.3 mL syringe**

5797D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*693.68	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 120 microgram/0.3 mL injection, 0.3 mL syringe**

5798E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*803.12	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 200 microgram/0.3 mL injection, 0.3 mL syringe**

5799F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1151.90	Mircera [RO]

**methoxy polyethylene glycol-epoetin beta 360 microgram/0.6 mL injection, 0.6 mL syringe**

5800G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1991.30	Mircera [RO]

■ **CARDIOVASCULAR SYSTEM**

■ **ANTIHYPERTENSIVES**

**OTHER ANTIHYPERTENSIVES**

*Antihypertensives for pulmonary arterial hypertension*

■ **AMBRISENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
- (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ambrisentan 10 mg tablet, 30**

5608E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1381.53	<sup>a</sup> Ambrisentan Viatris [AL] <sup>a</sup> PULMORIS [XT]	<sup>a</sup> Cipla Ambrisentan [ZU] <sup>a</sup> Volibris [ZE]

**ambrisentan 5 mg tablet, 30**

5607D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1381.53	<sup>a</sup> Ambrisentan Viatris [AL] <sup>a</sup> PULMORIS [XT]	<sup>a</sup> Cipla Ambrisentan [ZU] <sup>a</sup> Volibris [ZE]

▪ **AMBRISENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

**Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**ambrisentan 10 mg tablet, 30**

12186J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1381.53	<sup>a</sup> Ambrisentan Viatris [AL] <sup>a</sup> PULMORIS [XT]	<sup>a</sup> Cipla Ambrisentan [ZU] <sup>a</sup> Volibris [ZE]

**ambrisentan 5 mg tablet, 30**

12212R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	1381.53	<sup>a</sup> Ambrisentan Viatris [AL] <sup>a</sup> PULMORIS [XT]	<sup>a</sup> Cipla Ambrisentan [ZU] <sup>a</sup> Volibris [ZE]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Cessation of treatment (all patients)

**Clinical criteria:**

- Patient must be receiving PBS-subsidised treatment with this PAH agent, **AND**
- The treatment must be for the purpose of gradual dose reduction prior to ceasing therapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment. Treatment beyond 1 month will not be approved.

**bosentan 62.5 mg tablet, 60**

12140Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	169.30	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan Mylan [AF]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan RBX [RA]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.

**bosentan 62.5 mg tablet, 60**

12134P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	169.30	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan Mylan [AF]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan RBX [RA]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.



If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of the rapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

If patients will be taking 62.5mg for the first month then 125 mg, prescribers should request the first authority prescription of therapy with the 62.5 mg tablet strength, with the quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information and no repeats.

Prescribers should request the second authority prescription of therapy with the 125 mg tablet strengths, with a quantity for one month of treatment, based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

If patients will be taking 62.5mg for longer than 1 month, prescribers should request the first authority prescription of the rapy with the 62.5 mg tablet strength, with the quantity for one month of treatment and a maximum of 5 repeats based on the dosage recommendations in the TGA-approved Product Information.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**bosentan 125 mg tablet, 60**

5619R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	169.30	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan GH [GQ] <sup>a</sup> Bosentan RBX [RA]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan Mylan [AF]

**bosentan 62.5 mg tablet, 60**

5618Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	169.30	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan Mylan [AF]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan RBX [RA]

■ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.
- (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.
- (5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

#### **Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

#### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where multiple strengths of this drug are sought, the combined number of repeats sought for each strength should not exceed 5. If the optimal strength is still to be determined by the end of the initial PBS supply, prescribers are reminded that further supplies of the optimal strength may be obtained via the Continuing treatment listing via a telephone/online authority application.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**bosentan 62.5 mg tablet, 60**

12145F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	169.30	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan Mylan [AF]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan RBX [RA]

▪ **BOSENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
- (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)). Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

**Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where multiple strengths of this drug are sought, the combined number of repeats sought for each strength should not exceed 5. If the optimal strength is still to be determined by the end of the initial PBS supply, prescribers are reminded that further supplies of the optimal strength may be obtained via the Continuing treatment listing via a telephone/online authority application.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**bosentan 125 mg tablet, 60**

12149K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	169.30	<sup>a</sup> Bosentan APO [GX] <sup>a</sup> Bosentan GH [GQ] <sup>a</sup> Bosentan RBX [RA]	<sup>a</sup> BOSENTAN DR.REDDY'S [RI] <sup>a</sup> Bosentan Mylan [AF]

## ▪ EPOPROSTENOL

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

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

### **Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)



Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)  
 Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)  
 Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

**Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost

Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**epoprostenol 1.5 mg injection, 1 vial**

10117L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*1779.90	Veletri [JC]

**epoprostenol 500 microgram injection, 1 vial**

10130E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	30	5	..	*998.40	Veletri [JC]

■ **ILOPROST**

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class III drug and toxins induced PAH, or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
- (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the Therapeutic Goods Administration (TGA) approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)). Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)  
 Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)  
 Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - starting combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

**Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost  
 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost  
 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application,

**AND**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**iloprost 20 microgram/2 mL inhalation solution, 30 x 2 mL ampoules**

5751Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	349.59	Ventavis [BN]

▪ **MACITENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:



- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.
- (4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.
- (5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**macitentan 10 mg tablet, 30**

10136L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2596.02	Opsumit [JC]

▪ **MACITENTAN**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

**Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one prostanoid; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH, **AND**
- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

- (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**macitentan 10 mg tablet, 30**

12147H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2596.02	Opsumit [JC]

▪ **RIOCIGUAT**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 1 month following cessation of therapy, as recommended by the TGA-approved Product Information.

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have WHO Functional Class II, III or IV CTEPH, **AND**
- The condition must be inoperable by pulmonary endarterectomy; OR
- The condition must be recurrent or persistent following pulmonary endarterectomy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be at least 18 years of age.

CTEPH that is inoperable by pulmonary endarterectomy is defined as follows:

(a) Right heart catheterisation (RHC) demonstrating pulmonary vascular resistance (PVR) of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 90 days after start of full anticoagulation; and

(b) A mean pulmonary artery pressure (PAPmean) of greater than 25 mmHg at least 90 days after start of full anticoagulation.

CTEPH that is recurrent or persistent subsequent to pulmonary endarterectomy is defined as follows:

RHC demonstrating a PVR of greater than 300 dyn\*sec\*cm<sup>-5</sup> measured at least 180 days following pulmonary endarterectomy.

Where a RHC cannot be performed due to right ventricular dysfunction, an echocardiogram demonstrating the dysfunction must be documented in the patient's medical records.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

(a) the results from the 3 tests below, to establish baseline measurements, where available:

- (i) RHC composite assessment, and
- (ii) ECHO composite assessment, and
- (iii) 6 Minute Walk Test (6MWT); and

(b) confirmation of evidence of inoperable CTEPH including the pulmonary vascular resistance (PVR) value, a mean pulmonary artery pressure (PAPmean) and the starting date of full anticoagulation; or

(c) confirmation of evidence of recurrent or persistent CTEPH including the PVR value and the date that pulmonary endarterectomy was performed; or

(d) confirmation of an echocardiogram demonstrating right ventricular dysfunction.

Where it is not possible to perform all 3 tests above on clinical grounds, the expected test combination, in descending order of preference is:

- (1) RHC plus ECHO composite assessments;
- (2) RHC composite assessment plus 6MWT;
- (3) RHC composite assessment only.

In circumstance where a RHC cannot be performed on clinical grounds, the expected test combinations, in descending order of preference is:

- (1) ECHO composite assessment plus 6MWT;
- (2) ECHO composite assessment only.

Where fewer than 3 tests are able to be performed on clinical grounds, a patient specific reason outlining why the particular test(s) could not be conducted must be documented in the patient's medical records.

The test results provided must not be more than 2 months old at the time of application.

Prescriptions for dose titration must provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, The quantity approved must be based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 3 repeats.

The assessment of the patient's response to the initial 20-week course of treatment should be made following the preceding 16 weeks of treatment, in order to allow sufficient time for a response to be demonstrated.

Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must demonstrate stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

### **Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

### **Population criteria:**

- Patient must be at least 18 years of age.

Response to this drug is defined as follows:

For patients with two or more baseline tests, response to treatment is defined as two or more tests demonstrating stability or improvement of disease.

For patients with a RHC composite assessment alone at baseline, response to treatment is defined as a RHC result demonstrating stability or improvement of disease.

For patients with an ECHO composite assessment alone at baseline, response to treatment is defined as an ECHO result demonstrating stability or improvement of disease.

Test requirements to establish response to treatment for continuation of treatment are as follows:

The following list outlines the preferred test combination, in descending order, for the purposes of continuation of PBS-subsidised treatment:

- (1) RHC plus ECHO composite assessments plus 6MWT;
- (2) RHC plus ECHO composite assessments;
- (3) RHC composite assessment plus 6MWT;
- (4) ECHO composite assessment plus 6MWT;
- (5) RHC composite assessment only;
- (6) ECHO composite assessment only.

The results of the same tests as conducted at baseline should be documented in the patient's medical record with each continuing treatment application (i.e., every 6 months), except for patients who were able to undergo all 3 tests at baseline, and whose subsequent ECHO and 6MWT results demonstrate disease stability or improvement, in which case RHC can be omitted. In all other patients, where the same test(s) conducted at baseline cannot be performed for assessment of response on clinical grounds, a patient specific reason why the test(s) could not be conducted must be documented in the patient's medical records.

The test results conducted for continuing treatment must be no more than 2 months old at the time of application.

The assessment of the patient's response to the continuing 6 month courses of treatment should be made following the preceding 5 months of treatment, in order to allow sufficient time for a response to be demonstrated.

The maximum quantity per prescription must be based on the dosage recommendations in the TGA-approved Product Information and be limited to provide sufficient supply for 1 month of treatment.

A maximum of 5 repeats will be authorised.

Patients who fail to demonstrate disease stability or improvement to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic thromboembolic pulmonary hypertension (CTEPH)

Treatment Phase: Balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete a maximum of 20 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete a maximum of 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 20 or 24 weeks of treatment available under the above respective restriction, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Treatment criteria:**

- Must be treated in a centre with expertise in the management of CTEPH.

**Population criteria:**

- Patient must be at least 18 years of age.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**riociguat 500 microgram tablet, 42**

11001B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

**riociguat 1 mg tablet, 42**

10976Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

**riociguat 1.5 mg tablet, 42**

10989J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

**riociguat 2 mg tablet, 42**

10984D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

**riociguat 2.5 mg tablet, 42**

11002C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

▪ **RIOCIGUAT**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 3 months following cessation of therapy.

**Note** Special Pricing Arrangements apply.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must have been assessed by a physician with expertise in the management of PAH, **AND**
- Patient must have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
- (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions.

Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

#### **Clinical criteria:**

- Patient must have documented WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.



Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. Approvals for prescriptions for dose titration will provide sufficient quantity for dose titrations by 0.5 mg increments at 2-week intervals to achieve up to a maximum of 2.5 mg three times daily based on the dosage recommendations for initiation of treatment in the TGA-approved Product Information. No repeats will be authorised for these prescriptions. Approvals for subsequent authority prescription will be limited to 1 month of treatment, with the quantity approved based on the dosage recommendations in the TGA-approved Product Information, and a maximum of 4 repeats.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**riociguat 500 microgram tablet, 42**

11040C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

**riociguat 1 mg tablet, 42**

11054T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

**riociguat 1.5 mg tablet, 42**

11047K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

**riociguat 2 mg tablet, 42**

11038Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

**riociguat 2.5 mg tablet, 42**

11057Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1631.82	Adempas [BN]

▪ **SELEXIPAG**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial treatment - dose titration

**Clinical criteria:**

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Population criteria:**

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application. A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil. PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted. PAH (WHO Group 1 pulmonary hypertension) is defined as follows: (i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or (ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

**selexipag 200 microgram tablet, 140**

12258E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	8050.00	Upravi [JC]

▪ **SELEXIPAG**

- Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
- Note** No increase in the maximum quantity or number of units may be authorised.
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.
- Note** Special Pricing Arrangements apply.
- Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH
  - Heritable PAH
    - BMPR2 mutation
    - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
    - Other mutations
  - Drugs and toxins induced PAH
  - PAH associated with:
    - Connective tissue disease
    - Human immunodeficiency virus (HIV) infection
    - Portal hypertension
    - Congenital heart disease
    - Schistosomiasis

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial treatment - dose titration

**Clinical criteria:**

- Patient must have failed to achieve/maintain a WHO Functional Class II status with PAH agents (other than this agent) given as dual therapy, **AND**
- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must be for dose titration purposes with the intent of completing the titration within 12 weeks, **AND**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Population criteria:**

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.  
A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.  
For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.  
PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.  
PAH (WHO Group 1 pulmonary hypertension) is defined as follows:  
(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or  
(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

**selexipag 800 microgram tablet, 60**

12266N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	3450.00	Upravi [JC]

▪ **SELEXIPAG**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial treatment following dose titration

**Clinical criteria:**

- Patient must have WHO Functional Class III PAH at treatment initiation with this drug; OR
- Patient must have WHO Functional Class IV PAH at treatment initiation with this drug, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- Patient must have completed the dose titration phase, **AND**
- The treatment must not be as monotherapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Population criteria:**

- Patient must have had at least one PBS-subsidised PAH agent prior to this authority application.  
Select one appropriate strength (determined under the 'Initial treatment - dose titration' phase) and apply under this treatment phase (Initial treatment following dose titration) once only. Should future dose adjustments be required, apply under the 'Continuing treatment' restriction.  
A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.  
For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.  
PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.  
PAH (WHO Group 1 pulmonary hypertension) is defined as follows:  
(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) selexipag with one endothelin receptor antagonist, (ii) selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy'), **AND**
- The treatment must not be as monotherapy.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

For the purposes of administering this restriction, disease progression has developed if at least one of the following has occurred:

- (i) Hospitalisation due to worsening PAH;
- (ii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with worsening of WHO functional class status;
- (iii) Deterioration of aerobic capacity/endurance, consisting of at least a 15% decrease in 6-Minute Walk Distance from baseline, combined with the need for additional PAH-specific therapy;
- (iv) Initiation of parenteral prostanoid therapy or long-term oxygen therapy for worsening of PAH;
- (v) Need for lung transplantation or balloon atrial septostomy for worsening of PAH.

**selexipag 200 microgram tablet, 60**

12247N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

**selexipag 400 microgram tablet, 60**

12235Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

**selexipag 600 microgram tablet, 60**

12263K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

**selexipag 800 microgram tablet, 60**

12249Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

**selexipag 1 mg tablet, 60**

12259F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

**selexipag 1.2 mg tablet, 60**

12252W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Uptravi [JC]

**selexipag 1.4 mg tablet, 60**

12240F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Upravi [JC]

**selexipag 1.6 mg tablet, 60**

12265M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3450.00	Upravi [JC]

▪ **SILDENAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Clinical criteria:**

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**

- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) a completed authority prescription form; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:

- Connective tissue disease
- Human immunodeficiency virus (HIV) infection
- Portal hypertension
- Congenital heart disease
- Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

### **Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions.

Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **sildenafil 20 mg tablet, 90**

9547L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	95.81	<sup>a</sup> Revatio [UJ] <sup>a</sup> Sildenafil PHT APOTEX [TY]	<sup>a</sup> SILDATIO PHT [RW] <sup>a</sup> Sildenafil Sandoz PHT 20 [SZ]

▪ **SILDENAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))  
 Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

### **Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost  
 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

### **Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

### **Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost  
 Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

### **Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR



- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application,

**AND**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost  
Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**sildenafil 20 mg tablet, 90**

12144E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	95.81	<sup>a</sup> Revatio [UJ] <sup>a</sup> Sildenafil PHT APOTEX [TY]	<sup>a</sup> SILDATIO PHT [RW] <sup>a</sup> Sildenafil Sandoz PHT 20 [SZ]

▪ **TADALAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Clinical criteria:**

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs

Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat. PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tadalafil 20 mg tablet, 56**

1308W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	475.54	<sup>a</sup> Adcirca [LY] <sup>a</sup> TADALIS 20 [LR]	<sup>a</sup> Tadalca [CR]

▪ **TADALAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)  
Treatment Phase: Initial 1 (new patients)

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Clinical criteria:**

- Patient must have WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

(i) for why fewer than 3 tests are able to be performed on clinical grounds;

(ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that the test results are of a recency that the PAH physician making this authority application is satisfied that the diagnosis of PAH is current.

(5) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The test results must not be more than 6 months old at the time of application.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 (change)

**Clinical criteria:**

- Patient must have documented WHO Functional Class II PAH, or WHO Functional Class III PAH, **AND**
- Patient must have had their most recent course of PBS-subsidised treatment for this condition with a PAH agent other than this agent, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Swapping between PAH agents: Patients can access PAH agents through the PBS according to the relevant restrictions. Once these patients are approved initial treatment (monotherapy) with 1 of these 8 drugs, they may swap between PAH agents at any time without having to re-qualify for treatment with the alternate agent. This means that patients may commence treatment with the alternate agent, subject to that agent's restriction, irrespective of the severity of their disease at the time the application to swap therapy is submitted.

Applications to swap between the 8 PAH agents must be made under the relevant initial treatment (monotherapy) restriction. The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received their most recent course of PBS-subsidised treatment with this PAH agent for this condition, **AND**
- The treatment must be the sole PBS-subsidised PAH agent for this condition.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

A prior PAH agent is any of: ambrisentan, bosentan, macitentan, sildenafil, tadalafil, epoprostenol, iloprost, riociguat.

PAH agents are not PBS-subsidised for patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tadalafil 20 mg tablet, 60**

14281P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	509.51	Tadalafil 20 [LR]

▪ **TADALAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

(1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:

(a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or

(b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

## **Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**

- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

**Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**tadalafil 20 mg tablet, 56**

12151M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	475.54	<sup>a</sup> Adcirca [LY]	<sup>a</sup> Tadalca [CR]
					<sup>a</sup> TADALIS 20 [LR]	

▪ **TADALAFIL**

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

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

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 1 - combination therapy (dual or triple therapy, excluding selexipag) in an untreated patient

**Clinical criteria:**

- Patient must not have received prior PBS-subsidised treatment with a pulmonary arterial hypertension (PAH) agent, **AND**
- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient with class IV PAH.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Applications for authorisation of initial treatment must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

HSD (Public)



- (1) Confirm that the patient has a diagnosis of pulmonary arterial hypertension (PAH) in line with the following definition:
- (a) mean pulmonary artery pressure (mPAP) at least 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) no greater than 15 mmHg; or
  - (b) where right heart catheterisation (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure assessed by echocardiography (ECHO) is greater than 40 mmHg, with normal left ventricular function.

(2) Confirm that in forming the diagnosis of PAH, the following tests have been conducted:

- RHC composite assessment; and
- ECHO composite assessment; and
- 6 Minute Walk Test (6MWT)

Where it is not possible to perform all 3 tests on clinical grounds, the expected test combination, in descending order, is:

- RHC plus ECHO composite assessments;
- RHC composite assessment plus 6MWT;
- RHC composite assessment only.

In circumstances where RHC cannot be performed on clinical grounds, the expected test combination, in descending order, is:

- ECHO composite assessment plus 6MWT;
- ECHO composite assessment only.

(3) Document the findings of these tests in the patient's medical records, including, where relevant only, the reason/s:

- (i) for why fewer than 3 tests are able to be performed on clinical grounds;
- (ii) why RHC cannot be performed on clinical grounds - confirm this by obtaining a second opinion from another PAH physician or cardiologist with expertise in the management of PAH; document that this has occurred in the patient's medical records.

(4) Confirm that this authority application is not seeking subsidy for a patient with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** PAH (WHO Group 1 pulmonary hypertension) currently includes the following subtypes: Idiopathic PAH

- Heritable PAH
  - BMPR2 mutation
  - ALK-1, ENG, SMAD9, CAV1, KCNK3 mutations
  - Other mutations
- Drugs and toxins induced PAH
- PAH associated with:
  - Connective tissue disease
  - Human immunodeficiency virus (HIV) infection
  - Portal hypertension
  - Congenital heart disease
  - Schistosomiasis

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 2 - starting combination therapy (dual or triple therapy, excluding selexipag) in a treated patient where a diagnosis of pulmonary arterial hypertension is established through a prior PBS authority application

### **Clinical criteria:**

- Patient must currently have WHO Functional Class III PAH or WHO Functional Class IV PAH, **AND**
- Patient must have failed to achieve/maintain WHO Functional Class II status with at least one of the following PBS-subsidised therapies: (i) endothelin receptor antagonist monotherapy, (ii) phosphodiesterase-5 inhibitor monotherapy, (iii) prostanoid monotherapy, **AND**
- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR

- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid; triple combination therapy is treating a patient in whom monotherapy/dual combination therapy has been inadequate.

**Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Where a patient has had at least one PAH agent PBS-subsidised and the other(s) non-PBS-subsidised, apply under this 'Initial 2' treatment phase for the non-PBS-subsidised agent(s). Transitioning of the non-PBS to PBS-subsidised supply will be subject to restrictions in Initial 2. For the existing PBS-subsidised agent(s), the authority application(s) are to be through the Continuing treatment phase of that agent(s).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Initial 3 - changing to this drug in combination therapy (dual or triple therapy)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised combination therapy with at least this drug in the combination changing; combination therapy is not to commence through this Treatment phase listing, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Continuing treatment of combination therapy (dual or triple therapy, excluding selexipag)

**Clinical criteria:**

- The treatment must form part of dual combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of dual combination therapy consisting of: (i) one prostanoid, (ii) one phosphodiesterase-5 inhibitor; OR
- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) one prostanoid.

**Treatment criteria:**

- Patient must be undergoing continuing treatment of existing PBS-subsidised combination therapy (dual/triple therapy, excluding selexipag), where this drug in the combination remains unchanged from the previous authority application, **AND**
- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil; a prostanoid is one of: (f) epoprostenol, (g) iloprost. Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

**Note** If this authority application is to continue combination therapy, but with a change in at least one agent, the 'Initial 3 - change' treatment phase restriction of the new drug(s) outlines the continuing eligibility of that new drug.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Pulmonary arterial hypertension (PAH)

Treatment Phase: Triple therapy - Initial treatment or continuing treatment of triple combination therapy (including dual therapy in lieu of triple therapy) that includes selexipag

#### **Clinical criteria:**

- The treatment must form part of triple combination therapy consisting of: (i) one endothelin receptor antagonist, (ii) one phosphodiesterase-5 inhibitor, (iii) PBS-subsidised selexipag (referred to as 'triple therapy'); OR
- The treatment must form part of dual combination therapy consisting of either: (i) PBS-subsidised selexipag with one endothelin receptor antagonist, (ii) PBS-subsidised selexipag with one phosphodiesterase-5 inhibitor, as triple combination therapy with selexipag-an endothelin receptor antagonist-a phosphodiesterase-5 inhibitor is not possible due to an intolerance/contraindication to the endothelin receptor antagonist class/phosphodiesterase-5 inhibitor class (referred to as 'dual therapy in lieu of triple therapy').

#### **Treatment criteria:**

- Must be treated by a physician with expertise in the management of PAH, with this authority application to be completed by the physician with expertise in PAH.

The authority application for selexipag must be approved prior to the authority application for this agent.

For the purposes of PBS subsidy, an endothelin receptor antagonist is one of: (a) ambrisentan, (b) bosentan, (c) macitentan; a phosphodiesterase-5 inhibitor is one of: (d) sildenafil, (e) tadalafil.

PBS-subsidy does not cover patients with pulmonary hypertension secondary to interstitial lung disease associated with connective tissue disease, where the total lung capacity is less than 70% of predicted.

PAH (WHO Group 1 pulmonary hypertension) is defined as follows:

(i) mean pulmonary artery pressure (mPAP) greater than or equal to 25 mmHg at rest and pulmonary artery wedge pressure (PAWP) less than or equal to 15 mmHg; or

(ii) where a right heart catheter (RHC) cannot be performed on clinical grounds, right ventricular systolic pressure (RVSP), assessed by echocardiography (ECHO), greater than 40 mmHg, with normal left ventricular function.

The results and date of the RHC, ECHO and 6 MWT as applicable must be included in the patient's medical record. Where a RHC cannot be performed on clinical grounds, the written confirmation of the reasons why must also be included in the patient's medical record.

The maximum quantity authorised will be limited to provide sufficient supply for 1 month of treatment, based on the dosage recommendations in the TGA-approved Product Information.

A maximum of 5 repeats may be requested.

Tadalafil 20 mg with pack size of 60 tablets may be prescribed when used in a combination with endothelin receptor antagonist to provide sufficient supply of both medicines for the same number of days.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Authority applications for each agent in combination therapy should be made at the same time to reduce administrative handling. However, dosing of each agent need not occur simultaneously to be considered as 'combination therapy'.

#### **tadalafil 20 mg tablet, 60**

14271D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	509.51	Tadalafil 20 [LR]

## DERMATOLOGICALS

## ANTIPSORIATICS

### ANTIPSORIATICS FOR SYSTEMIC USE

*Psoralens for systemic use*

## METHOXSALEN

**Caution** This drug is for ex vivo administration and must not be injected directly into the patient.

**Note** The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

#### **Authority required (STREAMLINED)**

**10988**

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this PBS indication, **AND**
- Patient must have demonstrated a response to treatment with this drug if treatment is continuing beyond 6 months of treatment for the first time, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**

- Patient must be receiving the medical service as described in item 14249 of the Medicare Benefits Schedule.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

A response, for the purposes of administering this continuing restriction, is defined as attaining a reduction of at least 50% in the overall skin lesion score from baseline, for at least 4 consecutive weeks. Refer to the Product Information for directions on calculating an overall skin lesion score. The definition of a clinically significant reduction in the Product Information differs to the 50% requirement for PBS-subsidy. Response only needs to be demonstrated after the first six months of treatment

**methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials**

12154Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.08	5	..	*208.94	Uvadex [TQ]

▪ **METHOXSALEN**

**Caution** This drug is for ex vivo administration and must not to be injected directly into the patient.

**Note** The maximum quantity and maximum number of repeats are based on the following treatment protocol: one day of treatment per week for six weeks, then every two weeks for 12 weeks, then monthly thereafter. This differs from the Product Information. Requests for increased maximum quantities/maximum repeats will not be considered.

**Authority required (STREAMLINED)**

**10985**

Erythrodermic stage III-IVa T4 M0 Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have experienced disease progression while on at least one systemic treatment for this PBS indication prior to initiating treatment with this drug; OR
- Patient must have experienced an intolerance necessitating permanent treatment withdrawal to at least one systemic treatment for this PBS indication prior to initiating treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; OR
- The treatment must be in combination with peginterferon alfa-2a only if used in combination with another drug, **AND**
- Patient must be receiving the medical service as described in item 14247 of the Medicare Benefits Schedule, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

**Population criteria:**

- Patient must be aged 18 years or over.

**methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials**

12156T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.17	6	..	*417.88	Uvadex [TQ]

▪ **METHOXSALEN**

**Caution** This drug is for ex vivo administration and must not to be injected directly into the patient.

**Note** Up to 2 additional repeats to that stated in this listing may be sought.

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

**Authority required (STREAMLINED)**

**12531**

Chronic graft versus host disease

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received, at anytime prior to this pharmaceutical benefit within the same treatment episode, both: (i) this drug subsidised through the Initial treatment listing, (ii) the extracorporeal photopheresis-MBS benefit for initial treatment, **AND**
- Patient must have demonstrated a response to initial treatment with this drug (administered as part of MBS-subsidised extracorporeal photopheresis treatment) obtained through this drug's 'Initial treatment' PBS-listing for the same treatment episode.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition, **AND**
- Patient must not be undergoing re-treatment through this treatment phase immediately following a relapse - see 'Initial treatment' for resuming treatment following relapse.

HSD (Public)

**methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials**

12854M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	0.17	..	..	*417.88	Uvadex [TQ]

**▪ METHOXSALEN**

**Caution** This drug is for ex vivo administration and must not to be injected directly into the patient.

**Note** Current Medicare Benefits Schedule item numbers for extracorporeal photopheresis for the treatment of chronic graft-versus host disease are: 13761 and 13762.

**Note** A new treatment episode is considered to have begun when treatment with this drug/extracorporeal photopheresis follows a relapse of the condition. There is no limit on the number of new treatment cycles that may be commenced, but re-treatment following a relapse must not commence under 'Continuing treatment'.

**Note** A maximum quantity (vials) of 12 with 1 repeat prescription provides 24 doses of this drug. An additional 25<sup>th</sup> dose can be prescribed under this treatment phase by issuance of a further prescription made out for one vial with nil repeats. Alternatively, the 25<sup>th</sup> dose can be sought under the 'Continuing treatment' restriction. The 26<sup>th</sup> dose and onwards must be requested under the 'Continuing treatment' restriction.

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

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

**Authority required (STREAMLINED)****12546**

Chronic graft versus host disease

Treatment Phase: Initial treatment in a treatment episode

**Clinical criteria:**

- The condition must be inadequately responsive to systemic corticosteroid treatment at a therapeutic dose, but has never been treated with this drug; OR
- The condition must have relapsed within 8 weeks of prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis; OR
- The condition must have relapsed with each of the following conditions being met: (i) prior PBS-subsidised treatment with this drug administered via extracorporeal photopheresis last occurred at least 8 weeks ago, (ii) a subsequent trial of systemic corticosteroids at therapeutic doses has been completed.

**Treatment criteria:**

- Patient must be undergoing treatment with this drug that is being administered within at least one of: (i) the first 12 weeks of a treatment episode, (ii) the first 25 doses (inclusive of the 25<sup>th</sup> dose) of a treatment episode, **AND**
- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types, **AND**
- Patient must be undergoing treatment with this drug following allogeneic haematopoietic stem cell transplantation, **AND**
- Patient must be undergoing concurrent treatment with extracorporeal photopheresis as described in the Medicare Benefits Schedule for this condition.

**methoxsalen 200 microgram/10 mL injection, 12 x 10 mL vials**

12876Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	2507.28	Uvadex [TQ]

**▪ OTHER DERMATOLOGICAL PREPARATIONS****OTHER DERMATOLOGICAL PREPARATIONS***Agents for dermatitis, excluding corticosteroids***▪ OMALIZUMAB**

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe chronic spontaneous urticaria

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

**Clinical criteria:**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria), **AND**
- Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines, **AND**
- Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

- 1) a H2 receptor antagonist (150 mg twice per day); or
- 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or
- 3) doxepin (up to 25 mg three times a day)

If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.

A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include:
  - (i) demonstration of failure to achieve an adequate response to standard therapy; and
  - (ii) drug names and doses of standard therapies that the patient has failed; and
  - (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

### omalizumab 150 mg/mL injection, 1 mL syringe

11176F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*430.38	Xolair [NV]

### ■ OMALIZUMAB

**Note** A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.

**Note** Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### Authority required

Severe chronic spontaneous urticaria

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a clinical immunologist; OR
- Must be treated by an allergist; OR
- Must be treated by a dermatologist; OR
- Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU).

#### **Clinical criteria:**

- Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks per authorised course of treatment under this restriction.

### omalizumab 150 mg/mL injection, 1 mL syringe

11168T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*430.38	Xolair [NV]

## ■ SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### ■ PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

#### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

*Other anterior pituitary lobe hormones and analogues*

### ■ PEGVISOMANT

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)  
 Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs Programs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**pegvisomant 20 mg injection [1 vial] (&) inert substance diluent [1 syringe], 1 pack**

11177G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*529.32	Somavert [PF]

▪ **PEGVISOMANT**

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue.

Somatostatin analogues include octreotide, lanreotide and pasireotide

Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- 1) Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- 2) IGF-1 level is greater than the age- and sex-adjusted ULN.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance.

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

Two completed authority prescriptions should be submitted with the initial application for this drug. One prescription should be for the loading dose of 80 mg for a quantity of 4 vials of 20 mg with no repeats. The second prescription should be for subsequent doses, starting from 10 mg daily, and allowing dose adjustments in increments of 5 mg based on serum IGF-1 levels measured every 4 to 6 weeks in order to maintain the serum IGF-1 level within the age-adjusted normal range based on the dosage recommendations in the TGA-approved Product Information.

The authority application must be made in writing and must include:

- a) two completed authority prescription forms ; and
- b) a completed Acromegaly Pegvisomant initial PBS Authority Application - Supporting Information Form; and
- c) in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy, the date and result of IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy; and
- d) a recent result of the IGF-1 level and the date of assessment ; and
- e) demonstration of failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide

No increase in the maximum quantity or number of units may be authorised for the loading dose.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:

Department of Human Services  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with a PBS-subsidised somatostatin analogue, **AND**
- The treatment must cease if IGF-1 is not lower after 3 months of pegvisomant treatment at the maximum tolerated dose. Somatostatin analogues include octreotide, lanreotide and pasireotide

In a patient treated with radiotherapy, pegvisomant should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pegvisomant should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1).

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; and a copy of IGF-1 level taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of application.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**pegvisomant 10 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack**

11179J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3969.64	Somavert [PF]

**pegvisomant 15 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack**

11173C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3969.64	Somavert [PF]

**pegvisomant 20 mg injection [30 vials] (& inert substance diluent [30 syringes], 1 pack**

11181L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3969.64	Somavert [PF]

**HYPOTHALAMIC HORMONES**

*Somatostatin and analogues*

HSD (Public)



▪ LANREOTIDE

**Note** Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

**Authority required (STREAMLINED)**

**7025**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

**Authority required (STREAMLINED)**

**4575**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe**

5779E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2581.52	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

**lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe**

5777C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1699.46	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

**lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe**

5778D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2261.74	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

▪ LANREOTIDE

**Note** Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

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

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

**Authority required (STREAMLINED)**

**10061**

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

**Clinical criteria:**

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must be aged 18 years or older.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

**lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe**

11513Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2581.52	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

▪ **OCTREOTIDE**

**Authority required (STREAMLINED)**

**8161**

Acromegaly

**Clinical criteria:**

- The condition must be controlled with octreotide immediate release injections, **AND**
  - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
  - The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
  - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
- In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**

**5901**

Functional carcinoid tumour

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**5906**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 10 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10543X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*789.16	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

**octreotide 20 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10533J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1050.62	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

**octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

10550G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1207.32	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

▪ **OCTREOTIDE**

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

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

**Authority required (STREAMLINED)**

**10061**

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

**Clinical criteria:**

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must be aged 18 years or older.

WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

**octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

11893Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1207.32	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

▪ **OCTREOTIDE**

**Note** Pharmaceutical benefits that have the form octreotide 50 microgram/mL 5 x 1 mL ampoules can be substituted for octreotide 50 microgram/mL 5 x 1 mL vials in the case of a shortage.

**Authority required (STREAMLINED)**
**8165**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
  - Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
  - The treatment must be after failure of other therapy including dopamine agonists; OR
  - The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
  - The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
  - The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
  - The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
  - The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.
- In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**
**6390**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**
**6369**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 50 microgram/mL injection, 5 x 1 mL ampoules**

9508K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*186.84	<sup>a</sup> Octreotide GH [HQ] <sup>a</sup> Sandostatin 0.05 [NV]	<sup>a</sup> Octreotide (SUN) [RA]

**octreotide 50 microgram/mL injection, 5 x 1 mL vials**

14178F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	11	..	*656.10	<sup>a</sup> Octreotide Acetate Omega (Canada) [GQ]

**■ OCTREOTIDE**

**Note** Pharmaceutical benefits that have the form octreotide 500 microgram/mL 5 x 1 mL ampoules can be substituted for octreotide 500 microgram/mL 5 x 1 mL vials in the case of a shortage

**Authority required (STREAMLINED)**
**8165**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**

- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition. In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**

**6390**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**6369**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 500 microgram/mL injection, 5 x 1 mL ampoules**

9510M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*1870.38	<sup>a</sup> Octreotide GH [HQ] <sup>a</sup> Sandostatin 0.5 [NV]	<sup>a</sup> Octreotide (SUN) [RA]

**octreotide 500 microgram/mL injection, 5 x 1 mL vials**

14218H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	11	..	*1870.38	<sup>a</sup> Octreotide Acetate Omega (Canada) [GQ]

▪ **OCTREOTIDE**

**Note** Pharmaceutical benefits that have the form octreotide 100 microgram/mL 5 x 1 mL ampoules can be substituted for octreotide 100 microgram/mL 5 x 1 mL vials in the case of a shortage.

**Authority required (STREAMLINED)**

**8165**

Acromegaly

**Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks, **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment at a dose of 100 micrograms 3 time daily, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

**Authority required (STREAMLINED)**

**6390**

Functional carcinoid tumour

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**

- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**6369**

Vasoactive intestinal peptide secreting tumour (VIPoma)

**Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 2 months' therapy.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**octreotide 100 microgram/mL injection, 5 x 1 mL ampoules**

9509L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	18	11	..	*373.32	<sup>a</sup> Octreotide GH [HQ] <sup>a</sup> Sandostatin 0.1 [NV]	<sup>a</sup> Octreotide (SUN) [RA]

**octreotide 100 microgram/mL injection, 5 x 1 mL vials**

14219J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	11	..	*661.86	<sup>a</sup> Octreotide Acetate Omega (Canada) [GQ]

▪ **PASIREOTIDE EMBONATE**

**Caution** Careful monitoring of patients is mandatory due to high risk of developing hyperglycaemia

**Note** Special Pricing Arrangements apply.

**Authority required**

Acromegaly

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a mean growth hormone (GH) level greater than 1 microgram per litre or 3 mIU/L; OR
- Patient must have an age- and sex-adjusted insulin-like growth factor 1 (IGF-1) concentration greater than the upper limit of normal (ULN), **AND**
- The treatment must be after failure to achieve biochemical control with a maximum indicated dose of either 30 mg octreotide LAR or 120 mg lanreotide ATG every 28 days for 24 weeks; unless contraindicated or not tolerated according to the TGA approved Product Information, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

If treatment with either octreotide or lanreotide is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of contraindication.

If intolerance to either octreotide or lanreotide treatment developed during the relevant period of use which is of a severity to necessitate withdrawal of the treatment, the application must provide details of the nature and severity of this intolerance. Failure to achieve biochemical control after completion of a prior therapy with either octreotide or lanreotide is defined as:

- Growth hormone level greater than 1 mcg/L or 3 mIU/L; OR
- IGF-1 level is greater than the age- and sex-adjusted ULN.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR
- normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

The authority application must be made in writing and must include:

- a completed authority prescription form; and
- a completed Acromegaly PBS Authority Application - Supporting Information Form; and
- in a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy must be provided; the date and result of GH or IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided; and
- a recent result of GH or IGF-1 levels must be provided.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Acromegaly

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

**Population criteria:**

- Patient must be aged 18 years or older.

In a patient treated with radiotherapy, pasireotide should be withdrawn every 2 years in the 10 years after completion of radiotherapy for assessment of remission. Pasireotide should be withdrawn at least 8 weeks prior to the assessment of remission.

Biochemical evidence of remission is defined as:

- 1) Growth hormone (GH) levels of less than 1 mcg/L or 3 mIU/L; OR
- 2) normalisation of sex- and age- adjusted insulin-like growth factor 1 (IGF-1)

In a patient who has been previously treated with radiotherapy for this condition, the date of completion of radiotherapy and the GH and IGF-1 levels taken at the most recent two yearly assessment in the 10 years after completion of radiotherapy must be provided at the time of approval.

**Note** Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authorisation under this criterion should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**pasireotide (as embonate) 20 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10886Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7410.00	Signifor LAR [RJ]

**pasireotide (as embonate) 40 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10883T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7410.00	Signifor LAR [RJ]

**pasireotide (as embonate) 60 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack**

10882R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*7410.00	Signifor LAR [RJ]

**■ CALCIUM HOMEOSTASIS**  
**ANTI-PARATHYROID AGENTS**  
*Other anti-parathyroid agents*

**■ CINACALCET**

**Note** "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

**Authority required (STREAMLINED)**

**10067**

Secondary hyperparathyroidism

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a nephrologist.

**Clinical criteria:**

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

During the maintenance phase, iPTH should be monitored quarterly (measured at least 12 hours post dose) and dose adjusted as necessary to maintain an appropriate iPTH concentration.

During the maintenance phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment up to a maximum of 6 months supply, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

**cinacalcet 30 mg tablet, 28**

11887P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*39.50	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**cinacalcet 60 mg tablet, 28**

11886N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*79.02	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**cinacalcet 90 mg tablet, 28**

11885M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*118.52	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**■ CINACALCET**

**Note** "Sustained" means the abnormality was detected on at least 2 blood samples collected over a period of 2 to 4 months.

**Authority required**

Secondary hyperparathyroidism

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a nephrologist.

**Clinical criteria:**

- Patient must have chronic kidney disease, **AND**
- Patient must be on dialysis, **AND**
- Patient must have failed to respond to conventional therapy, **AND**
- Patient must have sustained hyperparathyroidism with iPTH of at least 50 pmol per L; OR
- Patient must have sustained hyperparathyroidism with iPTH of at least 15 pmol per L and less than 50 pmol per L and an (adjusted) serum calcium concentration at least 2.6 mmol per L.

During the titration phase, intact PTH (iPTH) should be monitored 4 weekly (measured at least 12 hours post dose) and dose titrated until an appropriate iPTH concentration is achieved.

During the titration phase, prescribers should request approval to allow sufficient supply for 4 weeks treatment at a time, with doses between 30 and 180 mg per day according to the patient's response and tolerability.

**cinacalcet 30 mg tablet, 28**

5621W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*39.50	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**cinacalcet 60 mg tablet, 28**

5622X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*79.02	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**cinacalcet 90 mg tablet, 28**

5623Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*118.52	<sup>a</sup> Cinacalcet Viatrix [AL]	<sup>a</sup> Pharmacor Cinacalcet [CR]

**■ ANTIINFECTIVES FOR SYSTEMIC USE**
**■ ANTIBACTERIALS FOR SYSTEMIC USE**
**MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS**
*Macrolides*
**■ AZITHROMYCIN**
**Authority required (STREAMLINED)**

**6356**

Mycobacterium avium complex infection

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**azithromycin 600 mg tablet, 8**

5616N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*110.76	Zithromax [PF]

NP

**■ ANTIMYCOBACTERIALS**
**DRUGS FOR TREATMENT OF TUBERCULOSIS**
*Antibiotics*

## ANTIINFECTIVES FOR SYSTEMIC USE

### ▪ RIFABUTIN

**Authority required (STREAMLINED)**

**6350**

Mycobacterium avium complex infection

**Clinical criteria:**

- Patient must be human immunodeficiency virus (HIV) positive.

**Authority required (STREAMLINED)**

**6356**

Mycobacterium avium complex infection

**Clinical criteria:**

- The treatment must be for prophylaxis, **AND**
- Patient must be human immunodeficiency virus (HIV) positive, **AND**
- Patient must have CD4 cell counts of less than 75 per cubic millimetre.

**rifabutin 150 mg capsule, 30**

9541E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	4	5	..	*525.84	Mycobutin [PF]

### ▪ ANTIVIRALS FOR SYSTEMIC USE

#### DIRECT ACTING ANTIVIRALS

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

### ▪ GANCICLOVIR

**Authority required (STREAMLINED)**

**15800**

Cytomegalovirus infection and disease

**Clinical criteria:**

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

**Authority required (STREAMLINED)**

**15814**

Cytomegalovirus infection and disease

**Clinical criteria:**

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.

**ganciclovir 500 mg injection, 5 vials**

5749N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*232.18	<sup>a</sup> Cymevene [PB]	<sup>a</sup> GANCICLOVIR SXP [XC]

### ▪ VALACICLOVIR

**Authority required (STREAMLINED)**

**5975**

Cytomegalovirus infection and disease

Treatment Phase: Prophylaxis

**Clinical criteria:**

- Patient must have undergone a renal transplant, **AND**
- Patient must be at risk of cytomegalovirus disease.

**valaciclovir 500 mg tablet, 100**

9568N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*200.00	<sup>a</sup> APX-Valaciclovir [TY]	<sup>a</sup> Valaciclovir APOTEX [GX]
			<sup>B</sup> 13.50	*213.50	<sup>a</sup> Valtrex [RW]	

### ▪ VALGANCICLOVIR

**Authority required (STREAMLINED)**

**15800**

Cytomegalovirus infection and disease

**Clinical criteria:**

- Patient must be a bone marrow transplant recipient at risk of cytomegalovirus disease.

**Authority required (STREAMLINED)**

**15814**

Cytomegalovirus infection and disease

**Clinical criteria:**

- Patient must be a solid organ transplant recipient at risk of cytomegalovirus disease.



**valganciclovir 50 mg/mL powder for oral liquid, 100 mL**

9655E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	11	5	..	*4346.10	Valcyte [PB]

**valganciclovir 450 mg tablet, 60**

9569P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*476.22	<sup>a</sup> Valganciclovir Sandoz [SZ]	<sup>a</sup> Valganciclovir Viatris [AL]

*Antivirals for treatment of HCV infections*

▪ **GLECAPREVIR + PIBRENTASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 8 weeks.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11332K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	1	..	16846.67	Maviret [VE]

NP

▪ **GLECAPREVIR + PIBRENTASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 16 weeks.  
The application must include details of the prior treatment regimen containing an NS5A inhibitor.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11333L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	16846.67	Maviret [VE]

NP

▪ **GLECAPREVIR + PIBRENTASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

**glecaprevir 100 mg + pibrentasvir 40 mg tablet, 84**

11345D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	16846.67	Maviret [VE]

NP

▪ **SOFOSBUVIR + VELPATASVIR**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Chronic hepatitis C infection

**Clinical criteria:**

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

### sofosbuvir 400 mg + velpatasvir 100 mg tablet, 28

11145N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	11875.00	Epclusa [GI]

### ▪ SOFOSBUVIR + VELPATASVIR + VOXILAPREVIR

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

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

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic hepatitis C infection

#### Clinical criteria:

- Patient must meet the criteria set out in the General Statement for Drugs for the Treatment of Hepatitis C, **AND**
- Patient must be taking this drug as part of a regimen set out in the matrix in the General Statement for Drugs for the Treatment of Hepatitis C, based on the hepatitis C virus genotype, patient treatment history and cirrhotic status, **AND**
- The treatment must be limited to a maximum duration of 12 weeks.

The application must include details of the prior treatment regimen containing an NS5A inhibitor.

### sofosbuvir 400 mg + velpatasvir 100 mg + voxilaprevir 100 mg tablet, 28

11665Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	1	2	..	11875.00	Vosevi [GI]

## ▪ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### ▪ ANTINEOPLASTIC AGENTS

#### ANTIMETABOLITES

##### *Pyrimidine analogues*

### ▪ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Acute Myeloid Leukaemia

#### Clinical criteria:

- The treatment must be used in combination with venetoclax (refer to Product Information for timing of azacitidine and venetoclax doses).

### azacitidine 100 mg injection, 1 vial

12771E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*359.66	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

### ▪ AZACITIDINE

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### Authority required

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
  - Patient must not have progressive disease.
- Up to 6 cycles will be authorised.

### azacitidine 100 mg injection, 1 vial

13028Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*359.66	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO]

<sup>a</sup> Azacitidine MSN [JU]

<sup>a</sup> Azacitidine Sandoz [SZ]

<sup>a</sup> Azacitidine-Teva [TB]

■ **AZACITIDINE**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be acute myeloid leukaemia confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must have 20% to 30% marrow blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) Classification.

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

- (a) bone marrow biopsy report demonstrating that the patient has acute myeloid leukaemia; and
- (b) full blood examination report.

**azacitidine 100 mg injection, 1 vial**

13036D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*359.66	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO]
					<sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Sandoz [SZ]

■ **AZACITIDINE**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be myelodysplastic syndrome confirmed through a bone marrow biopsy report and full blood examination, **AND**
- The condition must be classified as Intermediate-2 according to the International Prognostic Scoring System (IPSS); OR
- The condition must be classified as high risk according to the International Prognostic Scoring System (IPSS). Classification of the condition as Intermediate-2 requires a score of 1.5 to 2.0 on the IPSS, achieved with the possible combinations:
  - a. 11% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 0 to 1 cytopenias; OR
  - b. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 0 to 1 cytopenias; OR
  - c. 11% to 20% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
  - d. 5% to 10% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
  - e. 5% to 10% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias; OR
  - f. Less than 5% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), and 2 to 3 cytopenias.

Classification of the condition as high risk requires a score of 2.5 or more on the IPSS, achieved with the possible combinations:

- a. 21% to 30% marrow blasts with good karyotypic status (normal, -Y alone, del(5q) alone, del(20q) alone), and 2 to 3 cytopenias; OR
- b. 21% to 30% marrow blasts with intermediate (other abnormalities) or poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- c. 11% to 20% marrow blasts with poor karyotypic status (3 or more abnormalities or chromosome 7 anomalies), regardless of cytopenias; OR
- d. 11% to 20% marrow blasts with intermediate karyotypic status (other abnormalities), and 2 to 3 cytopenias.

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

- (a) The patient's International Prognostic Scoring System (IPSS) score

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

- (a) bone marrow biopsy report demonstrating that the patient has myelodysplastic syndrome; and
- (b) full blood examination report; and

(c) pathology report detailing the cytogenetics demonstrating intermediate-2 or high-risk disease according to the International Prognostic Scoring System (IPSS).

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

**azacitidine 100 mg injection, 1 vial**

13042K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*359.66	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

■ **AZACITIDINE**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required (STREAMLINED)**

**12986**

Acute Myeloid Leukaemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.

**azacitidine 100 mg injection, 1 vial**

13044M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*359.66	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

■ **AZACITIDINE**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Chronic Myelomonocytic Leukaemia

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be chronic myelomonocytic leukaemia confirmed through a bone marrow biopsy report and full blood examination report, **AND**
- The condition must have 10% to 29% marrow blasts without Myeloproliferative Disorder.

The first authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has chronic myelomonocytic leukaemia; and
- (b) details (date, unique identifying number/code or provider number) of the full blood examination report from an Approved Pathology Authority

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

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

- (a) bone marrow biopsy report demonstrating that the patient has chronic myelomonocytic leukaemia; and
- (b) full blood examination report

No more than 3 cycles will be authorised under this restriction in a patient's lifetime.

**azacitidine 100 mg injection, 1 vial**

9597D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	2	..	*359.66	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

▪ **AZACITIDINE**

**Caution** This is a category X drug and must not be given to pregnant women. Pregnancy must be avoided during treatment and for at least 6 months following cessation of therapy.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Chronic Myelomonocytic Leukaemia  
Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have progressive disease.  
Up to 6 cycles will be authorised.

**azacitidine 100 mg injection, 1 vial**

9598E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	14	5	..	*359.66	<sup>a</sup> Azacitidine Accord [OC] <sup>a</sup> AZACITIDINE EUGIA [YG] <sup>a</sup> Azacitidine MSN [JU] <sup>a</sup> Azacitidine-Teva [TB]	<sup>a</sup> Azacitidine Dr.Reddy's [RI] <sup>a</sup> Azacitidine Juno [JO] <sup>a</sup> Azacitidine Sandoz [SZ]

**CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES**

*Anthracyclines and related substances*

▪ **DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)**

**Authority required (STREAMLINED)**

**6234**

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive mucocutaneous involvement.

**Authority required (STREAMLINED)**

**6274**

Kaposi sarcoma

**Clinical criteria:**

- The condition must be AIDS-related, **AND**
- Patient must have a CD4 cell count of less than 200 per cubic millimetre, **AND**
- The condition must include extensive visceral involvement.

**doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial**

5705G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*553.68	<sup>a</sup> Caelyx [BX]	<sup>a</sup> Liposomal Doxorubicin SUN [RA]

**PROTEIN KINASE INHIBITORS**

*Janus-associated kinase (JAK) inhibitors*

▪ **RUXOLITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**13907**

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have received prior systemic steroid treatment for this condition, **AND**
- Patient must be one of the following: (i) refractory to steroid treatment, (ii) dependent on steroid treatment, (iii) intolerant to steroid treatment.

**Treatment criteria:**

- Must be treated by a haematologist; OR

- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

The severity of aGVHD is defined by the Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016).

Steroid-refractory disease is defined as:

- (a) progression after at least 3 days of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD; or
- (b) failure to achieve a partial response after 5 days at the time of initiation of high-dose systemic corticosteroid (methylprednisolone 2 mg/kg/day [or equivalent prednisone dose 2.5 mg/kg/day]) with or without calcineurin inhibitors for the treatment of Grade II-IV aGVHD.

Steroid-dependent disease is defined as failed corticosteroid taper involving either one of the following criteria:

- (a) an increase in the corticosteroid dose to methylprednisolone of at least 2 mg/kg/day (or equivalent prednisone dose of at least 2.5 mg/kg/day); or
- (b) failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum of 7 days.

Steroid intolerance is defined as a patient developing an intolerance of a severity necessitating treatment withdrawal.

Details of prior steroid use should be documented in the patient's medical records.

A patient must demonstrate a response 14 days after initiating treatment with ruxolitinib to be eligible for continuing treatment.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

- (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.
- (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**ruxolitinib 10 mg tablet, 56**

13232K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4750.00	Jakavi [NV]

**ruxolitinib 5 mg tablet, 56**

13243B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2375.00	Jakavi [NV]

▪ **RUXOLITINIB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**13892**

Grade II to IV acute graft versus host disease (aGVHD)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have responding disease compared with baseline after 14 days of treatment demonstrated by either a: (i) partial response (ii) complete response.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by an oncologist with allogeneic bone marrow transplantation experience; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types.

Response is defined as attaining a complete or partial response as assessed by Mount Sinai Acute GVHD International Consortium (MAGIC) criteria (Harris et al., 2016). Note that response is relative to the assessment of organ function affected by aGVHD prior to commencing initial treatment with ruxolitinib.

- (a) complete response is defined as a score of 0 for the aGVHD grade in all evaluable organs, indicating a complete resolution of all signs and symptoms of aGVHD, without the administration of any additional systemic therapies for any earlier progression, mixed response or non-response of aGVHD.

- (b) partial response is defined as an improvement of one stage, in at least one of the evaluable organs involved with aGVHD signs or symptoms, without disease progression in other organs or sites and without the administration of additional systemic therapies for any earlier progression, mixed response, or non-response of aGVHD.

The assessment of response must be documented in the patient's medical records.

Tapering the dose of corticosteroids should be considered in patients with responding disease. Following successful tapering of corticosteroids, tapering the dose of ruxolitinib can be initiated.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**ruxolitinib 10 mg tablet, 56**

13245D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4750.00	Jakavi [NV]

**ruxolitinib 5 mg tablet, 56**

13238R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	2375.00	Jakavi [NV]

*Other protein kinase inhibitors*

▪ **MIDOSTAURIN**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the initial maintenance treatment restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant.  
A maximum of 9 cycles will be authorised under this restriction in a lifetime.  
Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.  
If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.  
Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**midostaurin 25 mg capsule, 112**

11505M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18422.74	Rydapt [NV]

▪ **MIDOSTAURIN**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Maintenance therapy - Initial treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must have demonstrated complete remission after induction and consolidation chemotherapy in combination with midostaurin confirmed through a bone marrow biopsy pathology report, **AND**
- Patient must not be undergoing or have undergone a stem cell transplant, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority.

A maximum of 3 cycles will be authorised under this restriction in a lifetime.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;
- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
- Extramedullary leukaemia.

A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- confirmation that the patient is not undergoing or has not undergone a stem cell transplant; and
- confirmation that the patient does not have progressive disease; and
- details (date, unique identifying number/code or provider number) of a recent bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient is in complete remission; and
- details (date, unique identifying number/code or provider number) of the pathology test demonstrating that the condition was FMS tyrosine kinase 3 (FLT3) (ITD or TKD) mutation positive prior to commencing midostaurin.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

- a completed authority prescription form; and
- a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**midostaurin 25 mg capsule, 112**

11552B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18422.74	Rydapt [NV]

▪ **MIDOSTAURIN**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Acute Myeloid Leukaemia

Treatment Phase: Induction / Consolidation therapy

**Clinical criteria:**

- Patient must not have received prior chemotherapy as induction therapy for this condition; OR
- The treatment must be for consolidation treatment following induction treatment with midostaurin in combination with chemotherapy and the patient must not have progressive disease, **AND**
- The condition must be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive before initiating this drug for this condition confirmed through a pathology report from an Approved Pathology Authority, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The treatment must be in combination with standard intensive remission induction or consolidation chemotherapy for this condition.

A maximum of 6 cycles will be authorised under this restriction in a lifetime.

Standard intensive remission induction combination chemotherapy must include cytarabine and an anthracycline.

The prescriber must confirm whether the patient has FLT3 ITD or TKD mutation. The test result and date of testing must be provided at the time of application and documented in the patient's file.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Progressive disease monitoring via a complete blood count must be taken at the end of each cycle.

If abnormal blood counts suggest the potential for relapsed AML, a bone marrow biopsy must be performed to confirm the absence of progressive disease for the patient to be eligible for further cycles.

Progressive disease is defined as the presence of any of the following:

- Leukaemic cells in the CSF;
- Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;



- Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;
  - Extramedullary leukaemia.
- A patient who has progressive disease when treated with this drug is no longer eligible for PBS-subsidised treatment with this drug.

**midostaurin 25 mg capsule, 56**

11553C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	9211.37	Rydapt [NV]

**MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES**

*CD20 (Clusters of Differentiation 20) inhibitors*

▪ **RITUXIMAB**

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

**rituximab 500 mg/50 mL injection, 50 mL vial**

13101M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*432.36	<sup>a</sup> Riximyo [SZ] <sup>a</sup> Truxima [EW]	<sup>a</sup> Ruxience [PF]

▪ **RITUXIMAB**

**Note** Pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 2 x 10 mL vials and pharmaceutical benefits that have the form rituximab 100 mg/10 mL injection, 10 mL vial are equivalent for the purposes of substitution.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

**rituximab 100 mg/10 mL injection, 2 x 10 mL vials**

13082M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	..	..	*259.44	<sup>a</sup> Riximyo [SZ]	<sup>a</sup> Truxima [EW]

**rituximab 100 mg/10 mL injection, 10 mL vial**

13088W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	..	..	*259.44	<sup>a</sup> Ruxience [PF]

**OTHER ANTINEOPLASTIC AGENTS**

*Other antineoplastic agents*

▪ **SELINEXOR**

**Caution** This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and which disease activity parameters will be used to assess response, must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be documented for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 80 mg, 60 mg or 40 mg per week

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**selinexor 20 mg tablet, 16**

13085Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	9360.00	Xpovio [TG]

▪ **SELINEXOR**

**Caution** This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

HSD (Public)

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 100 mg per week

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must not have previously received this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 100 mg per week

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone; OR
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**selinexor 20 mg tablet, 20**

13086R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	11700.00	Xpovio [TG]

▪ **SELINEXOR**

**Caution** This drug is a Category D drug and must not be given to pregnant women. If this drug is taken during pregnancy, a teratogenic effect in humans cannot be ruled out.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment - Dose requirement of 160 mg per week

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**

- Patient must not have previously received this drug for this condition. Progressive disease is defined as at least 1 of the following:
  - (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
  - (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
  - (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
  - (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
  - (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
  - (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
  - (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy

**Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment - Dose requirement of 160 mg per week

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must be undergoing dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**selinexor 20 mg tablet, 32**

13104Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	18720.00	Xpovio [TG]

**IMMUNOSTIMULANTS**

**IMMUNOSTIMULANTS**  
*Colony stimulating factors*

**FILGRASTIM**

**Authority required (STREAMLINED)**

**7822**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**7843**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**6653**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

HSD (Public)

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

**6654**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

**6679**

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required (STREAMLINED)**

**6655**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required (STREAMLINED)**

**6680**

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required (STREAMLINED)**

**6621**

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required (STREAMLINED)**

**6640**

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 120 microgram/0.2 mL injection, 10 x 0.2 mL syringes**

5829T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*247.68	Nivestim [PF]

▪ **FILGRASTIM**

**Note** Pharmaceutical benefits that have the forms filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**7822**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**7843**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**6653**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

**6654**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

**6679**

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required (STREAMLINED)**

**6655**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required (STREAMLINED)**

**6680**

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required (STREAMLINED)**

**6621**

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required (STREAMLINED)**

**6640**

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 300 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

5742F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*234.92	<sup>a</sup> Nivestim [PF]

**filgrastim 300 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

2758E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*234.92	<sup>a</sup> Zarzio [SZ]

▪ **FILGRASTIM**

**Note** Pharmaceutical benefits that have the forms filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes and filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**7822**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**7843**

Chemotherapy-induced neutropenia

**Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

**Authority required (STREAMLINED)**

**6653**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be to facilitate harvest of peripheral blood progenitor cells for autologous transplantation into a patient with a non-myeloid malignancy who has had myeloablative or myelosuppressive therapy.

**Authority required (STREAMLINED)**

**6654**

Mobilisation of peripheral blood progenitor cells

**Clinical criteria:**

- The treatment must be in a normal volunteer for use in allogeneic transplantation.

**Authority required (STREAMLINED)**

**6679**

Assisting bone marrow transplantation

**Clinical criteria:**

- Patient must be receiving marrow-ablative chemotherapy prior to the transplantation.

**Authority required (STREAMLINED)**

**6655**

Assisting autologous peripheral blood progenitor cell transplantation

**Clinical criteria:**

- The treatment must be following marrow-ablative chemotherapy for non-myeloid malignancy prior to the transplantation.

**Authority required (STREAMLINED)**

**6680**

Severe congenital neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 100 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart, **AND**
- Patient must have had a bone marrow examination that has shown evidence of maturational arrest of the neutrophil lineage.

**Authority required (STREAMLINED)**

**6621**

Severe chronic neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 1,000 million cells per litre measured on 3 occasions, with readings at least 2 weeks apart; OR
- Patient must have neutrophil dysfunction, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics in the previous 12 months; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**Authority required (STREAMLINED)**

**6640**

Chronic cyclical neutropenia

**Clinical criteria:**

- Patient must have an absolute neutrophil count of less than 500 million cells per litre lasting for 3 days per cycle, measured over 3 separate cycles, **AND**
- Patient must have experienced a life-threatening infectious episode requiring hospitalisation and treatment with intravenous antibiotics; OR
- Patient must have had at least 3 recurrent clinically significant infections in the previous 12 months.

**filgrastim 480 microgram/0.5 mL injection, 10 x 0.5 mL syringes**

5744H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*376.60	<sup>a</sup> Nivestim [PF]

**filgrastim 480 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

2783L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	11	..	*376.60	<sup>a</sup> Zarzio [SZ]

▪ **LIPEGFILGRASTIM**

**Authority required (STREAMLINED)**

**7822**

Chemotherapy-induced neutropenia

**Clinical criteria:**

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

### **Authority required (STREAMLINED)**

**7843**

Chemotherapy-induced neutropenia

#### **Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

### **lipegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

10936N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	1116.25	Lonquex [TB]

## ▪ PEGFILGRASTIM

### **Authority required (STREAMLINED)**

**7822**

Chemotherapy-induced neutropenia

#### **Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must be at greater than 20% risk of developing febrile neutropenia; OR
- Patient must be at substantial risk (greater than 20%) of prolonged severe neutropenia for more than or equal to seven days.

### **Authority required (STREAMLINED)**

**7843**

Chemotherapy-induced neutropenia

#### **Clinical criteria:**

- Patient must be receiving chemotherapy with the intention of achieving a cure or a substantial remission, **AND**
- Patient must have had a prior episode of febrile neutropenia; OR
- Patient must have had a prior episode of prolonged severe neutropenia for more than or equal to seven days.

### **pegfilgrastim 6 mg/0.6 mL injection, 0.6 mL syringe**

9514R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	91.63	<sup>a</sup> Pelgraz [OC]	<sup>a</sup> Ziextenzo [SZ]

## *Interferons*

## ▪ INTERFERON GAMMA-1B

### **Authority required (STREAMLINED)**

**6222**

Chronic granulomatous disease

#### **Clinical criteria:**

- Patient must have frequent and severe infections despite adequate prophylaxis with antimicrobial agents.

### **interferon gamma-1b 2 million units (100 microgram)/0.5 mL injection, 6 x 0.5 mL vials**

5769P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	11	..	*1719.56	Imukin [LM]

## ▪ PEGINTERFERON ALFA-2A

**Caution** Treatment with peginterferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

**Note** Treatment centres are required to have access to the following appropriate specialist facilities for the provision of clinical support services for hepatitis C:

- a nurse educator/counsellor for patients; and
- 24-hour access by patients to medical advice; and
- an established liver clinic.

### **Authority required (STREAMLINED)**

**5004**

Chronic hepatitis C infection

#### **Treatment criteria:**

- Must be treated in an accredited treatment centre.

#### **Population criteria:**

- Patient must be aged 18 years or older, **AND**
- Patient must not be pregnant or breastfeeding, and must be using an effective form of contraception if female and of child-bearing age.

#### **Clinical criteria:**



- Patient must have compensated liver disease, **AND**
- Patient must not have received prior interferon alfa or peginterferon alfa treatment for hepatitis C, **AND**
- Patient must have a contraindication to ribavirin, **AND**
- The treatment must cease unless the results of an HCV RNA quantitative assay at week 12 (performed at the same laboratory using the same test) show that plasma HCV RNA has become undetectable or the viral load has decreased by at least a 2 log drop, **AND**
- The treatment must be limited to a maximum duration of 48 weeks.  
Evidence of chronic hepatitis C infection (repeatedly anti-HCV positive and HCV RNA positive) must be documented in the patient's medical records.

**peginterferon alfa-2a 135 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

9515T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	2	5	..	*947.02	Pegasys [XO]

**peginterferon alfa-2a 180 microgram/0.5 mL injection, 4 x 0.5 mL syringes**

9516W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
NP	2	5	..	*1096.72	Pegasys [XO]

*Other immunostimulants*

■ **PLERIXAFOR**

**Note** Applications for increased maximum quantities will only be authorised for patients with body weight greater than 100 kg.

**Authority required (STREAMLINED)**

**4549**

Mobilisation of haematopoietic stem cells

**Clinical criteria:**

- The treatment must be in combination with granulocyte-colony stimulating factor (G-CSF), **AND**
- Patient must have lymphoma; OR
- Patient must have multiple myeloma, **AND**
- Patient must require autologous stem cell transplantation, **AND**
- Patient must have failed previous stem cell collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and their peripheral blood CD34+ count is less than 10,000 per millilitre or less than 10 million per litre on the day of planned collection; OR
- Patient must be undergoing chemotherapy plus G-CSF mobilisation and the first apheresis has yielded less than 1 million CD34+ cells/kg.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**plerixafor 24 mg/1.2 mL injection, 1.2 mL vial**

10083Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	4016.84	<sup>a</sup> Mozobil [GZ] <sup>a</sup> PLERIXAFOR EUGIA [YG]	<sup>a</sup> Plerixafor ARX [XT]

■ **IMMUNOSUPPRESSANTS**

**IMMUNOSUPPRESSANTS**

*Selective immunosuppressants*

■ **ABATACEPT**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required (STREAMLINED)**

**14604**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR

- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

**abatacept 250 mg injection, 1 vial**

13725J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*787.20	Orencia [BQ]

▪ **ABATACEPT**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where

prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of authority application, medical practitioners should request the appropriate number of vials to provide sufficient drug, based on the weight of the patient, for a single infusion.

Up to a maximum of 4 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.



**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**abatacept 250 mg injection, 1 vial**

5605B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	262.40	Orencia [BQ]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**5795**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**5554**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 1 g/5 mL powder for oral liquid, 165 mL**

9500B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*489.02	<sup>a</sup> CellCept [RO]	<sup>a</sup> Pharmacor Mycophenolate [CR]

**mycophenolate mofetil 500 mg tablet, 50**

9502D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*152.76	<sup>a</sup> ARX-MYCOPHENOLATE [XT] <sup>a</sup> MycoCept [RF] <sup>a</sup> Mycophenolate Sandoz [SZ]	<sup>a</sup> Ceptolate [AF] <sup>a</sup> Mycophenolate GH [GQ] <sup>a</sup> Pharmacor Mycophenolate 500 [CR]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**5653**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**5600**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**mycophenolate mofetil 250 mg capsule, 100**

9501C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*152.88	<sup>a</sup> APO-Mycophenolate [TX] <sup>a</sup> Pharmacor Mycophenolate 250 [CR]	<sup>a</sup> Mycophenolate Sandoz [SZ]

▪ **MYCOPHENOLATE**

**Caution** Careful monitoring of patients is mandatory.

**Note** Management includes initiation, stabilisation and review of therapy as required.

**Authority required (STREAMLINED)**

**4084**

Prophylaxis of renal allograft rejection

Treatment Phase: Management

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**4095**

WHO Class III, IV or V lupus nephritis

Treatment Phase: Management

**Clinical criteria:**

- The condition must be proven by biopsy.

**Treatment criteria:**

- Must be treated by a nephrologist or in consultation with a nephrologist.  
The name of the consulting nephrologist must be included in the patient medical records.

**mycophenolate 180 mg enteric tablet, 120**

9503E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*171.58	<sup>a</sup> Mycophenolic Acid ARX [XT]	<sup>a</sup> Myfortic [NV]

**mycophenolate 360 mg enteric tablet, 120**

9504F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*343.12	<sup>a</sup> Mycophenolic Acid ARX [XT] <sup>a</sup> Myfortic [NV]	<sup>a</sup> MYCOTEX [CR]

**Tumor necrosis factor alpha (TNF-alpha) inhibitors**

▪ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Authority required (STREAMLINED)**

**14136**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

13228F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	444.17	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

12348X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	505.95	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

## ■ ADALIMUMAB

### Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Authority required (STREAMLINED)**

**14136**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

13212J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	444.17	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

12355G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	505.95	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

▪ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

#### **Authority required (STREAMLINED)**

##### **14136**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14286X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	545.68	<sup>a</sup> Abrilada [PF]

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

13293P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	567.42	<sup>a</sup> Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12417M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*545.68	<sup>a</sup> Amgevita [XT]

■ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

### Note Biosimilar prescribing policy

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL syringes and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL syringes are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### Treatment criteria:

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### Clinical criteria:

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### Population criteria:

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or



(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL syringes**

12431G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	444.17	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]	<sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL syringes**

9662M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	505.95	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

▪ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules.

HSD (Public)

However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 40 mg/0.4 mL pen devices and pharmaceutical benefits that have the form adalimumab 40 mg/0.8 mL pen devices are equivalent for the purposes of substitution

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**adalimumab 40 mg/0.4 mL injection, 2 x 0.4 mL pen devices**

12444Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	444.17	<sup>a</sup> Adalicip [LR] <sup>a</sup> Humira [VE] <sup>a</sup> Yuflyma [EW]	<sup>a</sup> Hadlima [RF] <sup>a</sup> Hyrimoz [SZ]

**adalimumab 40 mg/0.8 mL injection, 2 x 0.8 mL pen devices**

9663N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	505.95	<sup>a</sup> Abrilada [PF] <sup>a</sup> Hadlima [RF]	<sup>a</sup> Amgevita [XT] <sup>a</sup> Hyrimoz [SZ]

▪ **ADALIMUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

## (3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

## (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

## (5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

## (6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form adalimumab 20 mg/0.2 mL syringes and pharmaceutical benefits that have the form adalimumab 20 mg/0.4 mL syringes are equivalent for the purposes of substitution

**Note** Pharmaceutical benefits that have a pack size of 1 may be substituted for pharmaceutical benefits that have a pack size of 2, in combinations equivalent to the maximum quantity number of units.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records. The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**



- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections of appropriate strength, based on the weight of the patient, to provide a sufficient amount for two doses. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**adalimumab 20 mg/0.4 mL injection, 2 x 0.4 mL syringes**

14235F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	545.68	<sup>a</sup> Abrilada [PF]

**adalimumab 20 mg/0.2 mL injection, 2 x 0.2 mL syringes**

12406Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	567.42	<sup>a</sup> Humira [VE]

**adalimumab 20 mg/0.4 mL injection, 0.4 mL syringe**

12435L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*545.68	<sup>a</sup> Amgevita [XT]

▪ **ETANERCEPT**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules.

However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

## **Authority required (STREAMLINED)**

**14154**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**etanercept 25 mg injection [4 vials] (&) inert substance diluent [4 x 1 mL syringes], 1 pack**

13294Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*743.62	Enbrel [PF]

▪ **ETANERCEPT**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

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

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

## **Authority required (STREAMLINED)**

### **14154**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

13319B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	743.60	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

13308K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	743.60	<sup>a</sup> Enbrel [PF]

▪ **ETANERCEPT**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and

(ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline

measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

## **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**etanercept 25 mg injection [4 vials] (& inert substance diluent [4 x 1 mL syringes], 1 pack**

5734T	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1		..	..	371.81	Enbrel [PF]

▪ **ETANERCEPT**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.



## (2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

## (3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

## (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

## (5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

## (6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL syringes and pharmaceutical benefits that have the form etanercept injection 50 mg/mL, 4 x 1 mL pen devices are equivalent for the purposes of substitution.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

(a) an active joint count of at least 20 active (swollen and tender) joints; OR

(b) at least 4 active joints from the following list:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**

- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of injections to provide sufficient for four weeks of treatment. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**etanercept 50 mg/mL injection, 4 x 1 mL pen devices**

5735W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	743.60	<sup>a</sup> Enbrel [PF]

**etanercept 50 mg/mL injection, 4 x 1 mL syringes**

5733R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	743.60	<sup>a</sup> Enbrel [PF]

**▪ INFLIXIMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the

need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**

- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed Crohn Disease Activity Index (CDAI) Score; or
  - (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
  - (iii) the date of the most recent clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**infliximab 100 mg injection, 1 vial**

11389K	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or
- (ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-

subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

**infliximab 100 mg injection, 1 vial**

11424G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or
  - (ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or
  - (iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or
  - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years).
- Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease

may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition. A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrial of conventional therapies is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

Each application for subsequent continuing treatment with this drug must include an assessment of the patient's response to the prior course of therapy. If the response assessment is not provided at the time of application the patient will be deemed to have failed this course of treatment, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**infliximab 100 mg injection, 1 vial**

11448M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]



## ■ INFLIXIMAB

### Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11482H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required (STREAMLINED)**

**4524**

Acute severe ulcerative colitis

**Treatment criteria:**

- Must be treated by a gastroenterologist; OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology, or general medicine specialising in gastroenterology].

**Clinical criteria:**

- Patient must have received an infusion of infliximab for the treatment of this condition as a hospital inpatient no more than two weeks prior to the date of the authority application, **AND**
- Patient must be an adult aged 18 years or older, and prior to initiation of infliximab treatment in hospital must have been experiencing six or more bloody stools per day, plus at least one of the following: (i) Temperature greater than 37.8 degrees Celsius; (ii) Pulse rate greater than 90 beats per minute; (iii) Haemoglobin less than 105 g/L; (iv) Erythrocyte sedimentation rate greater than 30 mm/h; OR
- Patient must be a child aged 6 to 17 years inclusive, and prior to initiation of infliximab treatment in hospital must have had a Paediatric Ulcerative Colitis Activity Index (PUCAI) greater than or equal to 65, with the diagnosis confirmed by a gastroenterologist, or a consultant physician as specified below, **AND**
- Patient must have failed to achieve an adequate response to at least 72 hours treatment with intravenous corticosteroids prior to initiation of infliximab treatment in hospital.

**Population criteria:**

- Patient must be 6 years of age or older.

For adults aged 18 years or older, failure to achieve an adequate response to intravenous corticosteroid treatment is defined by the Oxford criteria where:

(i) If assessed on day 3, patients pass 8 or more stools per day or 3 or more stools per day with a C-reactive protein (CRP) greater than 45 mg/L

(ii) If assessed on day 7, patients pass 3 or more stools per day with visible blood.

For children aged 6 to 17 years, failure to achieve an adequate response to intravenous corticosteroids means a PUCAI score greater than 45 at 72 hours.

At the time of authority application, prescribers should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg.

Before administering infliximab to a child aged 6 to 17 years, the treating clinician must have consulted with a paediatric gastroenterologist or with an institution experienced in performance of paediatric colectomy. The name of the specialist or institution must be included in the patient's medical records.

Evidence that the patient meets the PBS restriction criteria must be recorded in the patient's medical records.

**infliximab 100 mg injection, 1 vial**

10067W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	1	..	*930.80	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more

immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required (STREAMLINED)**

**12069**

Severe Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11400B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*930.80	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

**■ INFLIXIMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an

alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years ); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retreatment of conventional therapies is not required.

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required (STREAMLINED)**

**9668**

Moderate to severe Crohn disease

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

The PCDAI assessment must be no more than 1 month old at the time of prescribing.

The PCDAI score must be documented in the patient's medical notes as the measurement of response to the prior course of therapy.

Patients are only eligible to receive subsequent continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

**infliximab 100 mg injection, 1 vial**

11449N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*930.80	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

■ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

HSD (Public)

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years). Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Authority applications for continuing treatment may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**infliximab 100 mg injection, 1 vial**

11459D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

■ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate



biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under the first continuing treatment restriction, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11497D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

■ **INFLIXIMAB**

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the

most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required (STREAMLINED)**

**9787**

Complex refractory Fistulising Crohn disease

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Patients are eligible to receive subsequent continuing treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

**infliximab 100 mg injection, 1 vial**

11423F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*930.80	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological

medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required (STREAMLINED)**

**14683**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- an ESR measurement no greater than 25 mm per hour; or
- a CRP measurement no greater than 10 mg per L; or
- an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required (STREAMLINED)**

**14701**

Ankylosing spondylitis

Treatment Phase: Subsequent continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11486M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	3	..	*930.80	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

**Authority required (STREAMLINED)**

**9188**

Severe psoriatic arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

The measurement of response to the prior course of therapy must have been conducted following a minimum of 12 weeks of therapy with this drug and must be documented in the patient's medical records.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11514B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*930.80	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommendation of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommendation of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years). An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

#### **Clinical criteria:**



- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or

(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11606W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the

full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required (STREAMLINED)**

**14504**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

**infliximab 100 mg injection, 1 vial**

11490R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*558.48	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

■ INFLIXIMAB

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a

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written-only authority application may not be practical in terms of providing timely access to continued treatment. Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

#### **Authority required (STREAMLINED)**

##### **14638**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

#### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

The date of the most recent treatment course, methotrexate dose, joint count and CRP and/or ESR must be documented in the patient's medical records. These values will be used for patients who transition to subcutaneous form of infliximab.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

If the requirement for concomitant treatment with methotrexate cannot be met because of a contraindication and/or severe intolerance, details must be documented in the patient's medical records.

**infliximab 100 mg injection, 1 vial**

13734W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	3	2	..	*558.48	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

■ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
  - (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
  - (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
  - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
- Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

#### **Authority required (STREAMLINED)**

**12042**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug; OR
- Patient must have demonstrated or sustained an adequate response to treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 while receiving treatment with this drug, if aged 6 to 17 years.

#### **Population criteria:**

- Patient must be 6 years of age or older.

Patients who have failed to maintain a partial Mayo clinic score of less than or equal to 2, with no subscore greater than 1, or, patients who have failed to maintain a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of less than 10 (if aged 6 to 17 years) with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are only eligible to receive continuing PBS-subsidised treatment with this drug in courses of up to 24 weeks at a dose of 5 mg per kg per dose providing they continue to sustain the response.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**infliximab 100 mg injection, 1 vial**

11461F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*930.80	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

■ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.



The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal. To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

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

**Note** Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

#### **Authority required (STREAMLINED)**

**8844**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Whole body

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

#### **Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required (STREAMLINED)**

**8940**

Severe chronic plaque psoriasis

Treatment Phase: Subsequent continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the First continuing treatment restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment per subsequent continuing treatment course authorised under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

The measurement of response to the prior course of therapy must be documented in the patient's medical notes.

Determination of response must be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**infliximab 100 mg injection, 1 vial**

11605T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	2	..	*930.80	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg

weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details of the contraindications/severe intolerances, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, details of the contraindication or intolerance including severity to methotrexate must be provided at the time of application and documented in the patient's medical records. The maximum tolerated dose of methotrexate must be provided at the time of the application, if applicable, and documented in the patient's medical records.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided at the time of application and documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) a total active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the active joint count, ESR and/or CRP result and date of results;
- (b) details of prior treatment, including dose and date/duration of treatment.
- (c) If applicable, details of any contraindications/intolerances.
- (d) If applicable, the maximum tolerated dose of methotrexate.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.
- Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**

- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the reasons why this criterion cannot be satisfied must be documented in the patient's medical records. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the active joint count, ESR and/or CRP result and date of result;
- (b) the most recent biological agent and the date of the last continuing prescription.
- (c) If applicable, the new baseline scores.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**infliximab 100 mg injection, 1 vial**

13723G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

#### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

Details of the NSAIDs trialled, their doses and duration of treatment must be provided at the time of application.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the reason a higher dose cannot be used must be provided.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, details of the contraindication must be provided.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, details of the nature and severity of this intolerance must be provided.

All relevant details must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the reason this criterion cannot be satisfied must be provided at the time of application.

The following must be provided at the time of application:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) details of the completed Exercise Program Self Certification Form (commencement and finish date); and
- (iv) baseline ESR and/or CRP level.

All supporting evidence, including the completed Exercise Program Self Certification Form must be kept in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.



To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR
- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The following must be provided at the time of application and documented in the patient's medical records:

(i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and

(ii) a baseline BASDAI score; and

(iii) a baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**infliximab 100 mg injection, 1 vial**

13765L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF]	<sup>a</sup> Renflexis [OQ]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with infliximab or adalimumab for moderate to severe ulcerative colitis; and infliximab for acute severe ulcerative colitis.

Where the term 'biological medicine' appears in the following notes and restrictions, it refers to infliximab and adalimumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 biological medicines at any one time.

From 1 June 2017, under the PBS, all paediatric patients will be able to commence a treatment cycle where they may trial each PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent.

Under these arrangements, within a single treatment cycle and depending on the disease severity, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who received PBS-subsidised biological medicine treatment prior to 1 June 2017 is considered to have started their treatment cycle as of 1 June 2017.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice. Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 June 2017.

(1) Initial treatment.

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy - Initial 1 treatment (new patient); or,
  - (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate agent - Initial 2 treatment (Change or Recommencement of treatment after a break in biological medicine therapy of less than 5 years ) [further details are under 'Swapping treatment' below]; or
  - (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy with the same agent - Initial 2 treatment (Change or Recommencement of treatment after a break in therapy of less than 5 years ); or
  - (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - recommencement of treatment after a break in biological medicine of more than 5 years).
- Treatment authorisations under Initial 1, Initial 2 and Initial 3 will be limited to provide for a maximum of 16 weeks of treatment for adalimumab and 14 weeks of treatment for infliximab. From 1 June 2017, a patient must be assessed for response to a course of initial PBS-subsidised treatment following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment with that drug under the First continuing treatment and Subsequent continuing treatment restrictions providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, Initial 2 or Initial 3 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Ulcerative Colitis Activity Index (PUCAI) Score, confirmation of ulcerative colitis disease), or the prior conventional therapies of corticosteroids or immunosuppressives.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving treatment (initial or continuing) at the time of the application. However, a patient cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle. To ensure a patient receives the maximum treatment opportunities allowed under these swapping arrangements, it is important that they are assessed for response to every course of treatment.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify under Initial 3 treatment restriction and meet the relevant criteria with respect to the indices of disease severity.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg (for a child, 1 to 2 mg/kg up to 40 mg) prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(1) a completed authority prescription form; and  
 (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes the following:

- (i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and
- (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

An adult patient who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A patient, aged 6 to 17 years, who has previously received induction therapy with PBS-subsidised treatment with this drug for an acute severe episode of ulcerative colitis in the last 4 months, and demonstrated an adequate response to induction therapy by achieving and maintaining a PUCAI score of less than 10 will not be required to demonstrate failure to prior treatment with a 5-aminosalicylate oral preparation and one of azathioprine, 6-mercaptopurine or oral steroids.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle; OR
- Patient must have previously received PBS-subsidised treatment with a biological medicine (adalimumab or infliximab) for this condition in this treatment cycle if aged 6 to 17 years, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle; OR

- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle more than once if aged 6 to 17 years.

**Population criteria:**

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If patients aged 6 to 17 years fail to respond to PBS-subsidised biological medicine treatment 3 times (twice with one agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6 if an adult patient; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score); OR
- Patient must have a Paediatric Ulcerative Colitis Activity Index (PUCAI) Score greater than or equal to 30 if aged 6 to 17 years; OR
- Patient must have previously received induction therapy with this drug for an acute severe episode of ulcerative colitis in the last 4 months and demonstrated an adequate response to induction therapy by achieving and maintaining a partial

Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a PUCAI score less than 10 (if aged 6 to 17 years).

**Population criteria:**

- Patient must be 6 years of age or older.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, or to be administered at 8-weekly intervals for patients who have received prior treatment for an acute severe episode, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic, partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) score must be no more than 4 weeks old at the time of application.

Where treatment for an acute severe episode has occurred, an adequate response to induction therapy needs to be demonstrated by achieving and maintaining a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1, or a Paediatric Ulcerative Colitis Activity Index (PUCAI) score less than 10 (if aged 6 to 17 years), within the first 12 weeks of receiving this drug for acute severe ulcerative colitis.

A partial Mayo clinic or Paediatric Ulcerative Colitis Activity Index (PUCAI) assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Details of the accepted toxicities including severity can be found on the Services Australia website.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or commencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

10196P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Population criteria:**

- Patient must be at least 18 years of age.

**Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- a completed authority prescription form; and
- a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- patient must have evidence of intestinal inflammation;
- patient must be assessed clinically as being in a high faecal output state;
- patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- faeces: higher than normal lactoferrin or calprotectin level; or
- diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.



If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

### **AND**

- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the first or subsequent continuing treatment restrictions. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

5754W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) for paediatric patients with adalimumab for severe refractory Crohn disease and infliximab for moderate to severe refractory Crohn disease. Where the term "biological medicines" appears in the following notes and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

From 1 August 2015, under the PBS, patients will be able to commence a treatment cycle where they may trial a PBS-subsidised biological medicine without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 August 2015 is considered to have started their treatment cycle as of 1 August 2015.

Within the same treatment cycle, a paediatric patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than twice.

Once a patient has either failed, or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date

of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 August 2015.

(1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised biological medicine therapy in this treatment cycle and wishes to commence such therapy - Initial 1 (new patient); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) biological medicine therapy and wishes to trial an alternate agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific biological medicine following a break in PBS-subsidised therapy with that agent - Initial 2 (Change or Re-commencement of treatment after a break in therapy of less than 5 years); or

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years - Initial 3 (Recommencement of treatment after a break in biological medicine of more than 5 years). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2015, a patient must be assessed for response to any course of initial PBS-subsidised biological therapy following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine therapy is approved, a patient with severe disease may swap if eligible to the alternate biological medicine within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Paediatric Crohn Disease Activity Index (PCDAI) Score, confirmation of Crohn disease), or the prior conventional therapies of corticosteroid therapy, immunosuppressive therapy or enteral nutrition.

A patient cannot swap to a biological medicine if they have failed to respond to prior treatment with that drug twice within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the PCDAI submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity under the Initial 3 restriction. A retrieval of conventional therapies is not required.

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#### **Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

#### **Clinical criteria:**

- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including: (i) a tapered course of steroids, starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) prednisolone (or equivalent), over a 6 week period; (ii) an 8 week course of enteral nutrition; or (iii) immunosuppressive therapy including azathioprine at a dose of at least 2 mg per kg daily for 3 or more months, or, 6-mercaptopurine at a dose of at least 1 mg

per kg daily for 3 or more months, or, methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months; OR

- Patient must have a documented intolerance of a severity necessitating permanent treatment withdrawal or a contra-indication to each of prednisolone (or equivalent), azathioprine, 6-mercaptopurine and methotrexate, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 preferably whilst still on treatment, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

- (i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application; and
- (ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy] or dates of enteral nutrition.

The PCDAI score should preferably be obtained whilst on conventional treatment but must be obtained within one month of the last conventional treatment dose.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition more than once in the current treatment cycle, **AND**

- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application -Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) Score calculation sheet; and

(ii) details of prior biological medicine treatment including details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed diagnosis of Crohn disease, defined by standard clinical, endoscopic and/or imaging features including histological evidence, **AND**
- Patient must have a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Application for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition which must be no more than one month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Moderate to severe Crohn disease

Treatment Phase: Balance of supply for paediatric patient

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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**Authority required**

Moderate to severe Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)]; OR
- Must be treated by a paediatrician; OR
- Must be treated by a specialist paediatric gastroenterologist.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have a reduction in PCDAI Score by at least 15 points from baseline value, **AND**
- Patient must have a total PCDAI score of 30 points or less, **AND**



- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 6 to 17 years inclusive.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Paediatric Crohn Disease PBS Authority Application - Supporting Information Form, which includes the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include a PCDAI assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**infliximab 100 mg injection, 1 vial**

5755X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

**■ INFLIXIMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate.

The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD

treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement. Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed. The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note Biosimilar prescribing policy** Prescribing of the biosimilar brand Brenzys is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; **AND** either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

### **Population criteria:**

- Patient must be at least 18 years of age.
- Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

Where a patient is changing from a biosimilar medicine for the treatment of this condition, the prescriber must provide baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the infliximab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with methotrexate at a dose of at least 7.5 mg weekly.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 3 mg per kg.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available

on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
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 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis  
 Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**infliximab 100 mg injection, 1 vial**

5757B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note** TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1 - new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a

severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

#### **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment (new patient or Commencement of treatment after more than 5 years break in therapy - Initial 1)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.



**Note** It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos).  
Or mailed to:  
Services Australia  
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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Change or Recommencement of treatment after a break in therapy of less than 5 years (Initial 2)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and  
(b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
- (ii) details of prior biological medicine treatment including details of date and duration of treatment.

The most recent fistula assessment must be no more than 1 month old at the time of application.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and this assessment must be submitted to the Department of Human Services no later than 4 weeks from the date that course was ceased.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

An assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (up to 6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for the first continuing treatment, must be submitted to the Department of Human Services no later than 1 month from the date of completion of this initial course of treatment.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

**Note** It is recommended that an application for the first continuing treatment is submitted to the Department of Human Services at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the first continuing treatment criteria for PBS-subsidised treatment with this drug.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos).  
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**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR

- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug.

An adequate response is defined as:

- (a) a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%; and/or
- (b) a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Fistulising Crohn Disease PBS Authority Application - Supporting Information Form which includes a completed Fistula Assessment form including the date of the assessment of the patient's condition.

The most recent fistula assessment must be no more than 1 month old at the time of application.

The application for first continuing treatment with this drug must include an assessment of the patient's response to the initial course of treatment. The assessment must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. This assessment must be submitted no later than 4 weeks from the cessation of that treatment course.

Where a response assessment is not provided within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum of 24 weeks of treatment with this drug will be authorised under this restriction.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
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HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease  
Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial treatment (new patient or Recommencement of treatment after more than 5 years break in therapy - Initial 1) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Change or Re-commencement of treatment after a break in therapy of less than 5 years (Initial 2) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment or subsequent continuing treatment restrictions to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses (Initial 1 or Initial 2 treatment) or 2 repeats (first Continuing or Subsequent Continuing treatment).

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

9654D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

**INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH ANKYLOSING SPONDYLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed for adult patients with the indication of ankylosing spondylitis (AS).

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Ankylosing spondylitis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

Treatment cycles:

Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a biological medicine while they continue to show a response to therapy. A patient who has been receiving PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, ixekizumab and secukinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 5-year break in PBS subsidy from all medicines with the PBS indication: 'Ankylosing spondylitis' before starting a new treatment cycle. The 5-year break is measured from the date of the last prescription for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 5 years has occurred, a further course of treatment may be commenced within the same treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for ankylosing spondylitis.

(2) Grandfather patients (bimekizumab).

A patient who commenced treatment with bimekizumab prior to 1 October 2024 for ankylosing spondylitis and who continues to receive treatment at the time of application, may qualify for treatment under the 'Grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

(3) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to proceed initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(4) Changing therapy.

Apply under the 'Initial 2' treatment listing. Once initial treatment with the first PBS-subsidised biological medicine is prescribed, a patient may swap to an alternate biological medicine without having to requalify with respect to prior NSAID therapy and exercise program requirements. Where a patient is changing from a biosimilar medicine the prescriber must submit baseline indices of disease severity (i.e. the erythrocyte sedimentation rate (ESR), the C-reactive protein (CRP) levels and the BASDAI). A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this initial 2 treatment authority application.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the BASDAI, ESR and/or CRP submitted with the first authority application for a biological medicine. To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Prescribers may provide new baseline measurements any time an 'Initial treatment' authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing. Prior NSAID and exercise therapies need not be re-trialled.

#### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

#### **Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Clinical criteria:**

- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have failed to achieve an adequate response following treatment with at least 2 non-steroidal anti-inflammatory drugs (NSAIDs), whilst completing an appropriate exercise program, for a total period of 3 months, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The application must include details of the NSAIDs trialled, their doses and duration of treatment.

If the NSAID dose is less than the maximum recommended dose in the relevant TGA-approved Product Information, the application must include the reason a higher dose cannot be used.

If treatment with NSAIDs is contraindicated according to the relevant TGA-approved Product Information, the application must provide details of the contraindication.

If intolerance to NSAID treatment develops during the relevant period of use which is of a severity to necessitate permanent treatment withdrawal, the application must provide details of the nature and severity of this intolerance.

The following criteria indicate failure to achieve an adequate response and must be demonstrated at the time of the initial application:

- (a) a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale; and
- (b) an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 10 mg per L.

The baseline BASDAI score and ESR or CRP level must be determined at the completion of the 3 month NSAID and exercise trial, but prior to ceasing NSAID treatment. All measurements must be no more than 4 weeks old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reason this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a completed Exercise Program Self Certification Form included in the supporting information form; and
- (iv) baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Details of the toxicities, including severity, which will be accepted for the purposes of administering this restriction can be found on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** For details on the appropriate minimum exercise program that will be accepted for the purposes of administering this restriction, please refer to the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed/ceased to respond to PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**

- Patient must not receive more than 18 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 5 years, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a patient is changing from PBS-subsidised treatment with a biosimilar medicine for this condition, the prescriber must submit baseline disease severity indicators with this application, in addition to the response assessment outlined below.

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of at least 5 years from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be either radiologically (plain X-ray) confirmed: (i) Grade II bilateral sacroiliitis; (ii) Grade III unilateral sacroiliitis, **AND**
- Patient must have at least 2 of the following: (i) low back pain and stiffness for 3 or more months that is relieved by exercise but not by rest; (ii) limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by a score of at least 1 on each of the lumbar flexion and lumbar side flexion measurements of the Bath Ankylosing Spondylitis Metrology Index (BASMI); (iii) limitation of chest expansion relative to normal values for age and gender, **AND**
- Patient must have a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 on a 0-10 scale that is no more than 4 weeks old at the time of application, **AND**
- Patient must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour that is no more than 4 weeks old at the time of application; OR

- Patient must have a C-reactive protein (CRP) level greater than 10 mg per L that is no more than 4 weeks old at the time of application; OR
- Patient must have a clinical reason as to why demonstration of an elevated ESR or CRP cannot be met and the application must state the reason, **AND**
- Patient must not receive more than 18 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (i) details (name of the radiology report provider, date of the radiology report and unique identifying number/code that links report to the individual patient) of the radiological report confirming Grade II bilateral sacroiliitis or Grade III unilateral sacroiliitis; and
- (ii) a baseline BASDAI score; and
- (iii) a baseline ESR and/or CRP level.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Ankylosing spondylitis

Treatment Phase: First continuing treatment

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An adequate response is defined as an improvement from baseline of at least 2 units (on a scale of 0-10) in the BASDAI score combined with at least 1 of the following:

- (a) an ESR measurement no greater than 25 mm per hour; or
- (b) a CRP measurement no greater than 10 mg per L; or
- (c) an ESR or CRP measurement reduced by at least 20% from baseline.

Where only 1 acute phase reactant measurement is supplied in the first application for PBS-subsidised treatment, that same marker must be measured and used to assess all future responses to treatment.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Ankylosing spondylitis

Treatment Phase: Initial treatment - Initial 1 (new patient), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patient) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 18 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 18 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 18 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Ankylosing spondylitis

Treatment Phase: Continuing treatment - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of ankylosing spondylitis.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**infliximab 100 mg injection, 1 vial**

5753T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

## ■ INFLIXIMAB

### Note TREATMENT OF ADULT PATIENTS WITH SEVERE PSORIATIC ARTHRITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) listed for adult patients with severe psoriatic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe Psoriatic Arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term 'biological medicine'.

A patient is eligible for PBS-subsidised treatment with only 1 of the biological medicines at any one time.

Under these arrangements, within a single treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient who received PBS-subsidised adalimumab, certolizumab pegol, etanercept, golimumab, guselkumab, infliximab, ixekizumab, secukinumab, tofacitinib or ustekinumab treatment prior to 1 October 2021 is considered to start their first cycle as of 1 October 2021.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence another cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe psoriatic arthritis.

#### (1) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or,

(ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or Recommencement of treatment after a break in therapy of less than 5 years) [further details are under 'Swapping therapy' below]; or,

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

A patient must be assessed for response to a course of PBS-subsidised initial treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

#### (2) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than the 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

#### (3) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to re-qualify with respect to either the indices of disease severity (i.e. erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP) level, and active joint count) or the prior non-biological therapy requirements. An authority application must be made under the 'Initial 2' treatment phase.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

#### (4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the indices of disease severity submitted with the first authority application for a biological medicine.

However, prescribers may provide new baseline measurements any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and these revised baseline measurements will be used to assess response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments. Therefore, where only an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active



joints (i.e. 20 or more active joints), response will be determined according to a reduction in the total number of active joints.

(5) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent course of treatment following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment restriction according to the criteria of the relevant restriction and index of disease severity. The application must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response to methotrexate at a dose of at least 20 mg weekly for a minimum period of 3 months, **AND**
- Patient must have failed to achieve an adequate response to sulfasalazine at a dose of at least 2 g per day for a minimum period of 3 months; OR
- Patient must have failed to achieve an adequate response to leflunomide at a dose of up to 20 mg daily for a minimum period of 3 months, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Where treatment with methotrexate, sulfasalazine or leflunomide is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

Where intolerance to treatment with methotrexate, sulfasalazine or leflunomide developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; and

either

(a) an active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 3 months treatment with methotrexate and 3 months treatment with sulfasalazine or leflunomide can be found on the Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au))

**Note** Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at [www.humanservices.gov.au](http://www.humanservices.gov.au)

Applications for authority to prescribe should be forwarded to:  
 Department of Human Services  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

- a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- a reduction in the number of the following major active joints, from at least 4, by at least 50%:
  - elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
 Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
 Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

#### **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form(s); and
- (2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, first or subsequent continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia

Complex Drugs  
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## **Authority required**

Severe psoriatic arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

## **Authority required**

Severe psoriatic arthritis

Treatment Phase: First continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an erythrocyte sedimentation rate (ESR) no greater than 25 mm per hour or a C-reactive protein (CRP) level no greater than 15 mg per L or either marker reduced by at least 20% from baseline; and

either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly.

Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form(s); and

(2) a completed Severe Psoriatic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe psoriatic arthritis

Treatment Phase: Continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of psoriatic arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the subsequent continuing Authority Required (in writing) treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

5756Y	Max.Qty	Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1		..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

▪ **INFLIXIMAB**

**Note TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, bimekizumab, etanercept, guselkumab, infliximab, ixekizumab, risankizumab, secukinumab, tildrakizumab, and ustekinumab treatment prior to 1 February 2019 is considered to start their first cycle as of 1 February 2019.

A patient receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus

psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Recommencement of treatment after a break in biological medicine of less than 5 years).

(iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab, and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab, 24 weeks of therapy for bimekizumab and 28 weeks of therapy for risankizumab, tildrakizumab and ustekinumab.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment and no later than 4 weeks from the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment.

The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab, adalimumab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle or have experienced treatment failure with that particular biological medicine that required permanent treatment withdrawal.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 4 weeks at the time of application.

#### **Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body (new patient)

#### **Clinical criteria:**

- Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, **AND**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

- A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.
- A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.
- The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:
  - the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and
  - details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**



- The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Face, hand, foot (new patient)

**Clinical criteria:**

- Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 6 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; (iii) ciclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks; (v) apremilast at a dose of 30 mg twice a day for at least 6 weeks; (vi) deucravacitinib at a dose of 6 mg once daily for at least 6 weeks, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

Where treatment with methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.

Where intolerance to treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.

Regardless of if a patient has a contraindication to treatment with either methotrexate, ciclosporin, apremilast, deucravacitinib, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.

The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:

(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:

(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment; or

(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment;

(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 4 weeks following cessation of each course of treatment.

(c) The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and

(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, ciclosporin, apremilast, deucravacitinib or acitretin can be found on the Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years)

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicines for this condition within this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**

- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:

- the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and
- details of prior biological treatment, including dosage, date and duration of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

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Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:
  - at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or
  - the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 22 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

**Treatment criteria:**

- Must be treated by a dermatologist.

The most recent PASI assessment must be no more than 4 weeks old at the time of application.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(a) a completed authority prescription form(s); and

(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area as assessed at baseline.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

**Note Biosimilar prescribing policy**

Prescribing of the biosimilar brand Inflectra or Renflexis is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or re-commencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or re-commencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 22 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 22 weeks treatment, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- The treatment must provide no more than the balance of up to 22 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Whole body

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as:

A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- a completed authority prescription form(s); and
- a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: First continuing treatment, Face, hand, foot

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- The treatment must be as systemic monotherapy (other than methotrexate), **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist.

An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:

- a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or
- a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity of vials, based on the weight of the patient, to provide for infusions at a dose of 5 mg per kg eight weekly. Up to a maximum of 2 repeats will be authorised.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form(s); and
- (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.

The most recent PASI assessment must be no more than 1 month old at the time of application.

Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.

The PASI assessment for first continuing or subsequent continuing treatment must be performed on the same affected area assessed at baseline.

It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Prescribers must include the proprietary name (brand) on the prescription to ensure the appropriate item is approved.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe chronic plaque psoriasis

Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the first continuing treatment, Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the first continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Whole body restriction to complete 24 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the subsequent continuing treatment Authority Required (in writing), Face, hand, foot restriction to complete 24 weeks treatment, **AND**

• The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions, **AND**

- The treatment must be as systemic monotherapy (other than methotrexate).

**Treatment criteria:**

- Must be treated by a dermatologist.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**infliximab 100 mg injection, 1 vial**

5758C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	186.16	<sup>a</sup> Inflectra [PF] <sup>a</sup> Renflexis [OQ]	<sup>a</sup> Remicade [JC]

*Interleukin inhibitors*

▪ **ANAKINRA**

**Note** This drug is not PBS-subsidised for conditions other than CAPS.

**Authority required (STREAMLINED)**

**5450**

Moderate to severe cryopyrin associated periodic syndromes (CAPS)

**Treatment criteria:**

- Must be treated by a rheumatologist or in consultation with a rheumatologist; OR

- Must be treated by a clinical immunologist or in consultation with a clinical immunologist. A diagnosis of CAPS must be documented in the patient's medical records.

**anakinra 100 mg/0.67 mL injection, 28 x 0.67 mL syringes**

10264F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1146.64	Kineret [ZO]

▪ **SILTUXIMAB**

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a diagnosis of iMCD consistent with the latest international, evidence-based consensus diagnostic criteria for this condition with the relevant diagnostic findings documented in the patient's medical records, **AND**
- The condition must not be, to the prescriber's best knowledge, any of the following diseases that can mimic iMCD: (i) human herpes virus-8 infection, (ii) an Epstein-Barr virus-lymphoproliferative disorder, (iii) an acute/uncontrolled infection (e.g. cytomegalovirus, toxoplasmosis, human immunodeficiency virus, tuberculosis) leading to inflammation with adenopathy, (iv) an autoimmune/autoinflammatory disease, (v) a malignant/lymphoproliferative disorder.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist, **AND**
- Patient must be undergoing treatment through this treatment phase once only in a lifetime, where the full number of repeats are prescribed; OR
- Patient must be undergoing treatment through this treatment phase for up to the first 5 doses in a lifetime, where the full number of repeats was not prescribed with the first prescription.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

**Note** The international, evidence-based consensus iMCD diagnostic criteria developed by an international working group of clinical experts lists various findings under 'Major' and 'Minor' diagnostic criteria that constitute a diagnosis of iMCD. At the time of writing, under these consensus criteria, diagnostic findings that meet: (i) both Major criteria and (ii) at least 2 of 11 Minor criteria including at least 1 laboratory abnormality and (iii) exclude various differential diagnoses, form a diagnosis of iMCD.

Details of these criteria are presented in Table 2 of the following literature article:

Fajgenbaum DC, Uldrick TS, Bagg A, Frank D et. al. International, evidence-based consensus diagnostic criteria for HHV-8-negative/idiopathic multicentric Castleman disease. **Blood** 2017; 129(12): 1646-1657.

Where updates to these diagnostic criteria have occurred since the publication, refer to the latest version.

Do not contact the PBS-administrator to discuss whether an individual patient meets these consensus criteria.

**Authority required**

Idiopathic multicentric Castleman disease (iMCD)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a medical physician working under the supervision of a haematologist.

Prescribe the most efficient combination of vials/strengths based on the patient's body weight to keep any amount of unused drug to a minimum.

**siltuximab 100 mg injection, 1 vial**

12916T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	4	..	*1558.56	Sylvant [RJ]

**siltuximab 400 mg injection, 1 vial**

12922D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	4	..	*6234.20	Sylvant [RJ]

▪ **TOCILIZUMAB**

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for adults with severe active rheumatoid arthritis. This listing is a temporary listing and is only to be used to transfer patients back to tocilizumab from another biological medicine, where treatment was changed due to unavailability of tocilizumab due to the critical medicines shortage.

The term biological medicine refers to the tumour necrosis factor (TNF) alfa antagonists (adalimumab, certolizumab pegol, etanercept, golimumab, infliximab), the chimeric anti-CD20 monoclonal antibody (rituximab), the interleukin-6 inhibitor (tocilizumab), the T-cell co-stimulation modulator (abatacept) and the Janus kinase (JAK) inhibitors (baricitinib, tofacitinib, upadacitinib).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment. Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or
- (b) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

12791F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

HSD (Public)



**tocilizumab 400 mg/20 mL injection, 20 mL vial**

12763R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

12775J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

▪ **TOCILIZUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should

be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Authority required (STREAMLINED)**

**14164**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

- (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurement of joint count provided with the initial treatment application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

13305G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	203.73	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

13339C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	405.39	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

13324G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*164.38	Actemra [RO]

■ **TOCILIZUMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious

HSD (Public)

infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under

Initiating subsidy:

(i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or

(ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

(iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment.

Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine.

'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

**Note** Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Authority required (STREAMLINED)**

**14621**

Severe active rheumatoid arthritis

Treatment Phase: Subsequent continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition under the First continuing treatment restriction; OR
- Patient must have received this drug under this treatment phase as their most recent course of PBS-subsidised biological medicine, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records and must be no more than 4 weeks old at the time of the authority application.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority approval is required for each strength requested.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

13684F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	203.73	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

13715W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	405.39	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

13690M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*164.38	Actemra [RO]

▪ **TOCILIZUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a

treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

#### **Authority required (STREAMLINED)**

**14093**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response

assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

13330N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*407.46	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

13299Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*810.78	Actemra [RO]

■ **TOCILIZUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and
- (ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Authority required (STREAMLINED)**

**14093**

Systemic juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

Determination of whether a response has been demonstrated to initial and subsequent courses of treatment will be based on the baseline measurements of disease severity provided with the initial treatment application.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of prescribing and must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested. Up to a maximum of 5 repeats will be authorised.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

The patient remains eligible to receive continuing treatment with the same biological medicine in courses of up to 24 weeks providing they continue to sustain an adequate response. It is recommended that a patient be reviewed in the month prior to completing their current course of treatment.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

13304F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*328.76	Actemra [RO]

▪ **TOCILIZUMAB**

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be under 18 years of age.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment.

Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients who have severe active juvenile idiopathic arthritis.

This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage. Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 4 (Temporary listing - change of treatment from another biological medicine to tocilizumab after resolution of the critical shortage of tocilizumab)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have been receiving PBS-subsidised treatment with tocilizumab for this condition prior to 1 November 2021, **AND**
- Patient must have been receiving PBS-subsidised treatment with a biological medicine for this condition in place of tocilizumab due to the critical supply shortage of tocilizumab, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and



(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient has received 12 weeks or more of therapy with the alternative biological medicine as their most recent treatment, evidence of a response must be provided.

If a prescriber wishes to switch therapy back to tocilizumab upon resolution of the shortage, evidence demonstrating a response to the alternative biological medicine is not required, if the patient has not completed 12 weeks of treatment.

Prescribers must note on the change/recommencement authority application form that the patient is unable to demonstrate response due to insufficient treatment length and the patient is switching to tocilizumab as the shortage has been resolved.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) an active joint count of fewer than 10 active (swollen and tender) joints; or

(b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or

(c) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, and etanercept for patients over 18 years who have a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. This listing is a temporary listing and is only to be used to transfer patients currently receiving PBS-subsidised treatment with tocilizumab to another biological medicine, where tocilizumab is not available due to the current critical medicines shortage.

Alternative biological medicine refers to adalimumab and etanercept.

Should it be necessary to continue treatment with the alternative biological medicine, applications must be made under the relevant 'First continuing - Temporary listing' PBS listing.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

12796L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

12802T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

12794J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

▪ **TOCILIZUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active systemic juvenile idiopathic arthritis (sJIA).

Treatment cycles:

From 1 May 2012, a patient receiving PBS-subsidised tocilizumab therapy is considered to be in a treatment cycle. Under these arrangements, within a single treatment cycle, a patient may:

(i) continue to receive long-term treatment with PBS-subsidised tocilizumab while they continue to show an adequate response to therapy, and

(ii) fail to respond, or to sustain a response, to PBS-subsidised tocilizumab twice.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, will not be considered as a treatment failure.

Where treatment has resulted in an inadequate response on 2 occasions, a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active systemic juvenile idiopathic arthritis' before starting a new treatment cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised tocilizumab treatment was prescribed to the date of the first application for initial treatment with tocilizumab under the new treatment cycle.

Prescribing under the correct 'Treatment Phase' listing for the authority application.

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active systemic juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority prescription for continuing treatment is not to be written on the same day as initial treatment.

(3) Recommencement of treatment after a break of less than 12-months in PBS-subsidised therapy, within the same treatment cycle.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count, fever and/or CRP level and platelet count) will not need to be restated, except if the patient has had a break in therapy of more than 12 months.

(4) Baseline measurements to determine response.

Whether an adequate response to treatment has been demonstrated or not will be based on the relative change from relevant baseline measurements of the joint count, fever and/or CRP level and platelet count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial authority application is provided with a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with a biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. A demonstration of response to the current treatment should be documented in the patient's medical records at the time treatment is ceased. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have polyarticular course disease which has failed to respond adequately to oral or parenteral methotrexate at a dose of at least 15 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; OR
- Patient must have polyarticular course disease and have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have refractory systemic symptoms, demonstrated by an inability to decrease and maintain the dose of prednisolone (or equivalent) below 0.5 mg per kg per day following a minimum of 2 months of therapy, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be under 18 years of age.

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

The following criteria indicate failure to achieve an adequate response to prior methotrexate therapy in a patient with polyarticular course disease and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list of major joints:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response to prior therapy in a patient with refractory systemic symptoms and must be demonstrated in the patient at the time of the initial application:

- (a) an active joint count of at least 2 active joints; and
- (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or
- (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN).

The assessment of response to prior treatment must be documented in the patient's medical records.

The baseline measurements of joint count, fever and/or CRP level and platelet count must be performed preferably whilst on treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be used to determine response for all subsequent continuing treatments.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with other treatments is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active systemic juvenile idiopathic arthritis; and
- (b) the details of prior treatment including dose and duration of treatment.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

#### **Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (retial or recommencement of treatment after a break of less than 12 months)

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in the previous 12 months, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug more than once during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be under 18 years of age.

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

An adequate response to treatment is defined as:

(a) in a patient with polyarticular course disease:

(i) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(ii) a reduction in the number of the following major active joints, from at least 4, by at least 50%:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

(b) in a patient with refractory systemic symptoms:

(i) absence of fever greater than 38 degrees Celsius in the preceding seven days; and/or

(ii) a reduction in the C-reactive protein (CRP) level and platelet count by at least 30% from baseline; and/or

(iii) a reduction in the dose of corticosteroid by at least 30% from baseline.

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

The following reports must be documented in the patient's medical records where appropriate:

- (a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to retial or recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was prescribed in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break of more than 12 months)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from this drug for this condition, **AND**
- Patient must have polyarticular course disease and the condition must have at least one of: (a) an active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active joints from the following list of major joints: i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth); OR
- Patient must have refractory systemic symptoms and the condition must have (a) an active joint count of at least 2 active joints; and (b) persistent fever greater than 38 degrees Celsius for at least 5 out of 14 consecutive days; and/or (c) a C-reactive protein (CRP) level and platelet count above the upper limits of normal (ULN), **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**Population criteria:**

- Patient must be under 18 years of age.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active systemic juvenile idiopathic arthritis.

The following reports must be documented in the patient's medical records where appropriate:

(a) pathology reports detailing C-reactive protein (CRP) level and platelet count.

The most recent systemic juvenile idiopathic arthritis assessment must be no more than 4 weeks old at the time of application.

At the time of authority application, the medical practitioner must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for two infusions (one month's supply). A separate authority approval is required for each strength requested.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to 2 courses of treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in the current treatment cycle. A serious adverse reaction of a severity requiring permanent withdrawal of treatment is not considered as a treatment failure.

**Authority required**

Systemic juvenile idiopathic arthritis

Treatment Phase: Balance of supply for Initial treatment - Initial 1 (new patient) or Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) or Initial 3 (recommencement of treatment after a break of more than 12 months)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (retrial or recommencement of treatment after a break of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under Initial 3 (recommencement of treatment after a break of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks therapy available under Initial 1, 2 or 3 treatment.

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

1481Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

HSD (Public)

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

1482B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

1476Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

▪ **TOCILIZUMAB**

**Note TREATMENT OF PATIENTS WITH SEVERE ACTIVE JUVENILE IDIOPATHIC ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits listed with the indication of severe active juvenile idiopathic arthritis.

Where the term 'biological medicine' appears in notes and restrictions, it refers to any PBS benefit where the PBS indication specifies: Severe active juvenile idiopathic arthritis. Some benefits are not biological medicines, but are small molecules. However, for administrative purposes, these benefits are included within the term "biological medicine".

Treatment cycles:

From 1 December 2023, a patient receiving PBS-subsidised biological medicine is considered to be in a treatment cycle where they may switch to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- (i) continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- (ii) fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Where treatment has resulted in an inadequate response on 3 occasions a treatment cycle is considered to have been completed and there must be a 12-month break in PBS-subsidy from all biological medicines with the PBS indication 'severe active juvenile idiopathic arthritis' before starting a new treatment cycle.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was prescribed to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine immediately prior to 1 December 2023 is considered to be in their first cycle as of 1 December 2023. A patient who has had a break in biological medicine treatment of at least 12 months immediately prior to making a new application, on or after 1 December 2023, will commence a new treatment cycle under the Initial 3 treatment restriction.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of less than 12 months has occurred a further course of treatment may be commenced within the same treatment cycle.

Where treatment has resulted in an inadequate response on fewer than 3 occasions in a treatment cycle and where a break in therapy of more than 12 months has occurred a new treatment cycle must be commenced.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Prescribing under the correct 'Treatment Phase' listing for the authority application:

(1) Initial treatment.

Apply under the 'Initial 1' treatment listing where the patient has never received a biological medicine for 'severe active juvenile idiopathic arthritis'.

(2) Continuing treatment.

Apply under the 'Continuing treatment' listing where the patient is experiencing an adequate response as defined in the restriction where there has been no change in prescribed biological medicine. Under no circumstance is continuing treatment to precede initial treatment. An authority application for continuing treatment is not to be made on the same day as initial treatment.

(3) Changing therapy.

Apply under the 'Initial 2' treatment listing. The indices of disease severity (joint count) or the prior non-biological medicine therapy requirements will not need to be restated, except if the patient has had a break in therapy of more than 12 months who would then need to requalify under the initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application.

However, they cannot change to a particular biological medicine if it has failed to provide the patient with an adequate response within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany the initial 2 authority application.

(4) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count provided with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is provided within a treatment cycle and the eligibility for continuing treatment should be assessed according to the revised baseline measurement.

(5) Recommencement of treatment after a 12-month break in PBS-subsidised therapy.

Apply under the 'Initial 3' treatment listing.

(6) Withdrawal of treatment after sustained remission.

Withdrawal of treatment with biological medicine should be considered in a patient who has achieved and sustained complete remission of disease for 12 months. An assessment of demonstration of response to the current treatment should

be conducted at the time treatment is ceased and the results retained in the patient's records. These results must be provided to Services Australia if subsequent authority applications are required.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have demonstrated severe intolerance of, or toxicity due to, methotrexate; OR
- Patient must have demonstrated failure to achieve an adequate response to 1 or more of the following treatment regimens: (i) oral or parenteral methotrexate at a dose of at least 20 mg per square metre weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (ii) oral or parenteral methotrexate at a dose of 20 mg weekly, alone or in combination with oral or intra-articular corticosteroids, for a minimum of 3 months; (iii) oral methotrexate at a dose of at least 10 mg per square metre weekly together with at least 1 other disease modifying anti-rheumatic drug (DMARD), alone or in combination with corticosteroids, for a minimum of 3 months, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be under 18 years of age.

Severe intolerance to methotrexate is defined as intractable nausea and vomiting and general malaise unresponsive to manoeuvres, including reducing or omitting concomitant non-steroidal anti-inflammatory drugs (NSAIDs) on the day of methotrexate administration, use of folic acid supplementation, or administering the dose of methotrexate in 2 divided doses over 24 hours.

Toxicity due to methotrexate is defined as evidence of hepatotoxicity with repeated elevations of transaminases, bone marrow suppression temporally related to methotrexate use, pneumonitis, or serious sepsis.

If treatment with methotrexate alone or in combination with another DMARD is contraindicated according to the relevant TGA-approved Product Information, details must be documented in the patient's medical records.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be documented in the patient's medical records.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

- (a) an active joint count of at least 20 active (swollen and tender) joints; OR
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to prior treatment must be documented in the patient's medical records.

The joint count assessment must be performed preferably whilst still on DMARD treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

- (a) the date of assessment of severe active juvenile idiopathic arthritis; and
- (b) details of prior treatment including dose and duration of treatment.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Use of alternative DMARDs in children is dependent on approval by the Therapeutic Goods Administration as age restrictions may apply.

## **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)

### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

An adequate response to treatment is defined as:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The assessment of response to treatment must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 12 months have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 12 months or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

Active joints are defined as:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measurements must be no more than 4 weeks old at the time of this application and must be documented in the patient's medical records.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of active joints, the response must be demonstrated on the total number of active joints.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority approval is required for each strength requested. Up to a maximum of 3 repeats will be authorised.

The following information must be provided by the prescriber at the time of application and documented in the patient's medical records:

(a) the date of assessment of severe active juvenile idiopathic arthritis; and

(b) the date of the last continuing prescription.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

The assessment of the patient's response to the most recent course of biological medicine must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response

assessment is not conducted within these timeframes, the patient will be deemed to have failed that most recent course of treatment in this treatment cycle.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

#### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply

#### **Treatment criteria:**

- Must be treated by a paediatric rheumatologist; OR
- Patient must be undergoing treatment under the supervision of a paediatric rheumatology treatment centre.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

#### **tocilizumab 200 mg/10 mL injection, 10 mL vial**

10056G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

#### **tocilizumab 400 mg/20 mL injection, 20 mL vial**

10064Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

#### **tocilizumab 80 mg/4 mL injection, 4 mL vial**

10077J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

## ■ TOCILIZUMAB

### **Note** TREATMENT OF ADULT PATIENTS WITH A HISTORY OF JUVENILE IDIOPATHIC ARTHRITIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab, etanercept and tocilizumab for a patient over 18 years who has a history of juvenile idiopathic arthritis with onset prior to the age of 18 years. Where the term 'biological medicine' appears in notes and restrictions, it refers to adalimumab, etanercept and tocilizumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 3 biological medicines at any one time.

From 1 April 2014, a patient receiving PBS-subsidised biological medicine therapy is considered to be in a treatment cycle where they may swap to an alternate biological medicine without having to experience a disease flare. Under these interchangeability arrangements, within a single treatment cycle, a patient may:

- continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy; and
- fail to respond or to sustain a response to each PBS-subsidised biological medicine once only. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a single treatment cycle and they must have, at a minimum, a 5 year break in PBS-subsidised biological medicine therapy before they are eligible to receive further PBS-subsidised biological medicine therapy.

The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised biological medicine was approved to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

A patient who received PBS-subsidised biological medicine treatment immediately prior to 1 April 2014 is considered to be in their first cycle as of 1 April 2014. A patient who has had a break in biological medicine treatment of at least 24 months immediately prior to making a new application, on or after 1 April 2014, will commence a new treatment cycle under the Initial 3 treatment restriction

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of less than 24 months may commence a further course of treatment within the same treatment cycle under the Initial 2 treatment restriction.

A patient who has failed fewer than 3 trials of a biological medicine in a treatment cycle and who has a break in therapy of more than 24 months must commence a new treatment cycle under the Initial 3 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine therapy after 1 April 2014.



**(1) Initial treatment.**

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 - New patient); or
- (ii) a patient has received prior PBS-subsidised biological medicine therapy (initial or continuing) and wishes to trial an alternate medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine of less than 24 months) [further details are under 'Swapping therapy' below]; or
- (iii) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 24 months with the same medicine (Initial 2 - Change or recommencement of treatment after a break in biological medicine therapy of less than 24 months); or
- (iv) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 24 months (Initial 3 - recommencement of treatment after a break in biological medicine of more than 24 months).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy. A patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy and conducted no later than 4 weeks from the cessation of the treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment.

**(2) Continuing treatment.**

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to Services Australia where applicable. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Adalimumab and infliximab only:

Following the completion of an initial treatment course with a specific biological medicine, a patient remains eligible to receive up to 24 weeks per course of continuing treatment under the First continuing treatment and Subsequent continuing treatment restrictions with that drug providing they continue to sustain the response.

It is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

**(3) Swapping therapy.**

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (joint count and ESR/CRP) or the prior non-biological medicine therapy requirements, except if the patient has had a break in therapy of more than 24 months who would then need to requalify under the Initial 3 restrictions with respect to the indices of disease severity.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified in the relevant restriction.

**(4) Baseline measurements to determine response.**

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements of the joint count submitted with the first authority application for a biological medicine. However, prescribers may provide a new baseline measurement any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

**(5) Recommencement of treatment after 24 months break in PBS-subsidised therapy.**

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological medicine therapy of at least 24 months, must qualify under the Initial 3 restriction and meet the relevant criteria and index of disease severity.

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with each of at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly and one of which must be: (i) hydroxychloroquine at a dose of at least 200 mg daily; or (ii) leflunomide at a dose of at least 10 mg daily; or (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with each of at least 2 of the following DMARDs: (i)

hydroxychloroquine at a dose of at least 200 mg daily; and/or (ii) leflunomide at a dose of at least 10 mg daily; and/or (iii) sulfasalazine at a dose of at least 2 g daily; OR

- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

If methotrexate is contraindicated according to the TGA-approved Product Information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

- (a) an active joint count of at least 20 active (swollen and tender) joints; or
- (b) at least 4 active joints from the following list:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than one month old at the time of initial application.

If the above requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** The Department of Human Services website ([www.humanservices.gov.au](http://www.humanservices.gov.au)) has details of the toxicities, including severity, which will be accepted for the following purposes:

- (a) exempting a patient from the requirement to undertake a minimum 3 month trial of methotrexate at a 20 mg weekly dose;
- (b) substituting azathioprine, cyclosporin or sodium aurothiomalate for another DMARD as part of the 6 month intensive DMARD trial;
- (c) exempting a patient from the requirement for a 6 month trial of intensive DMARD therapy.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have a documented history of severe active juvenile idiopathic arthritis with onset prior to the age of 18 years, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recently approved PBS-subsidised biological medicine for this condition; OR
- Patient must not have received PBS-subsidised biological medicine for at least 5 years if they failed or ceased to respond to PBS-subsidised biological medicine treatment 3 times in their last treatment cycle, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either (a) a total active joint count of at least 20 active (swollen and tender) joints; or (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Active joints are defined as:

- elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
- shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count must be no more than 4 weeks old at the time of this application.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- completed authority prescription form(s); and
- a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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**Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after break of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR

- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **Authority required**

Severe active juvenile idiopathic arthritis

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### **Population criteria:**

- Patient must be aged 18 years or older.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

- (a) an active joint count of fewer than 10 active (swollen and tender) joints; or
- (b) a reduction in the active (swollen and tender) joint count by at least 50% from baseline; or
- (c) a reduction in the number of the following active joints, from at least 4, by at least 50%:
  - (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or
  - (ii) shoulder, cervical spine and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response will be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be demonstrated on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker will be used to determine response.

The authority application must be made in writing and must include:

- (1) completed authority prescription form(s); and
- (2) a completed Juvenile Idiopathic Arthritis PBS Authority Application - Supporting Information Form.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for one infusion. A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Where the most recent course of PBS-subsidised treatment with this drug was approved under either Initial 1, Initial 2, or Initial 3 treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

If a patient fails to respond to PBS-subsidised biological medicine treatment 3 times (once with each agent) they will not be eligible to receive further PBS-subsidised biological medicine therapy in this treatment cycle.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active juvenile idiopathic arthritis  
Treatment Phase: Continuing Treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restriction.

**Note** Authority approval for sufficient therapy to complete the balance of supply may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

10058J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

10072D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

10081N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

■ **TOCILIZUMAB**

**Note PBS AUTHORITY APPLICATIONS FOR SEVERE ACTIVE RHEUMATOID ARTHRITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) subsidy of the biological medicines for adults with severe active rheumatoid arthritis. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of: 'severe active rheumatoid arthritis'.

Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

Only one biological medicine is to be PBS-subsidised at any one time for rheumatoid arthritis.

Upon 5 inadequate responses to biological medicines with the specific PBS indication of 'severe active rheumatoid arthritis', further subsidy is to cease. Where a particular biological medicine has provided an inadequate response, it must not be subsidised again.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Stevens Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered a treatment failure.

(1) Selecting the correct 'Treatment phase' listing to apply under Initiating subsidy:

- (i) Apply through 'Initial 1 treatment' where a patient has received no prior PBS-subsidised biological medicine treatment; or
- (ii) Apply through 'Initial 2 treatment' where one of the following occurs: (a) PBS-subsidised treatment has at least been initiated through any Initial 1 listing, but the prescribed biological medicine is changing, (b) there has been a break in biological medicine of less than 24 months, but resumption of treatment is with the same biological medicine last prescribed, (c) there has been a break in biological medicine of less than 24 months and resumption of treatment is with a different biological medicine to that last prescribed, (d) treatment with rituximab has occurred within the past 24 months and is the most recent therapy prescribed leading up to this authority application, irrespective of the length in time elapsed between the 2 non-rituximab bDMARDs administered before and after rituximab.

Initial 2 does not require markers of inflammation/joint count to be re-established - those recorded in the first Initial 1 application can remain as baseline measures. Prerequisite DMARD treatments need not be re-proven to be inadequate. The prescribed biological medicine may be changed at any time, regardless of whether the current prescribed biological medicine has been obtained through Initial treatment or Continuing treatment. However, the change in biological medicine cannot be back to the same biological medicine where that medicine has provided an inadequate response.

- (iii) Apply through 'Initial 3 treatment' where treatment is recommencing following a break in PBS-subsidised therapy of at least 24 months. Initial 3 requires current markers of inflammation/joint count to be re-established. Prerequisite DMARD treatments need not be re-proven to be inadequate. PBS-subsidised therapy in this instance can include rituximab where prescribed as the most recent treatment - the 24 month break in therapy is from the second dose of the prior rituximab course.

Response assessment to any course of PBS-subsidised biological therapy must follow a minimum of 12 weeks of therapy. Applications made on the same day for Initial treatment and Continuing treatment clearly do reflect this requirement.

Where a response assessment is not conducted with a 'Continuing treatment' application, the biological medicine will be assumed to have failed, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment. Authority applications for patients who experienced adverse reaction necessitating permanent treatment withdrawal should be submitted through 'Initial 2 treatment' or 'Initial 3 treatment'. Indicate where the adverse reaction has occurred in the authority application.

Continuing subsidy:

Apply under a 'Continuing treatment' phase listing only where treatment has initiated through an 'Initial treatment' listing and measures of disease control (i.e. ESR/CRP/joint count) demonstrate response following at least 12 weeks of treatment. Continuing treatment should never precede Initial treatment where the same biological medicine is being prescribed.

The description of 'Continuing treatment' means 'Continuing treatment of severe rheumatoid arthritis with the same biological medicine'. Where treatment of severe rheumatoid arthritis is continuing with a different biological medicine, 'Continuing treatment' is not to be interpreted as meaning 'Continuing treatment of severe rheumatoid arthritis with a different biological medicine' - see 'Initial 2 treatment' where continuing treatment is with a different biological medicine. 'Continuing treatment' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Where continuing treatment is divided into 'First continuing' and 'Subsequent continuing', the next authority application following immediately after any 'Initial treatment' authority application is to be through 'First continuing'. Following this, the next authority application is to occur under the 'Subsequent continuing' treatment phase. Assuming the drug continues to provide an adequate response, 'Subsequent continuing' is to be accessed repeatedly until the prescribed biological medicine is either changed, stops providing an adequate response, or the patient takes a break in treatment.

Balance of Supply listings:

Maximum quantities and the number of repeats stated in a PBS-listing are values that prescribers may seek up to, but are not obligated to prescribe. From time to time, there may be particular reasons why a prescriber may elect not to request the full maximum quantity listed, or, the full number of repeat prescriptions. Where this occurs, the intent of Balance of Supply treatment phase listings is to circumvent the need for another written-only authority application to be completed, as a written-only authority application may not be practical in terms of providing timely access to continued treatment.

Apply under a 'Balance of Supply' treatment phase (where available) when either the full maximum quantity or repeat prescriptions available under a particular treatment phase, was not requested and where the biological medicine has had insufficient time to demonstrate an adequate response. Where the preceding supply has been adequate to provide at least 12 weeks of treatment and has resulted in an adequate response, it may be more practical to access further treatment under 'Continuing treatment'.

(2) Baseline measurements to determine response.

Determination of response to treatment must be based on baseline measurements of the joint count, ESR and/or CRP provided with the first authority application for a biological medicine. However, prescribers may provide new baseline measurements demonstrating elevation of both joint count and markers of inflammation any time that an initial treatment authority application is provided and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline must be used for all subsequent continuing treatment applications. Therefore, where an ESR or CRP level is provided at baseline, an ESR or CRP level respectively must be used to determine response. Similarly, where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints.

Applications under the Initial 1 treatment restriction for a new patient must include a joint count and ESR and/or CRP measured at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. The results must be no more than 4 weeks old at the time of application.

Applications under the Initial 3 treatment restriction for recommencement of treatment after a break in biological medicine of more than 24 months must include a joint count and ESR and/or CRP measurement that is no more than 4 weeks old at the time of application.

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#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 1 (new patient)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with disease modifying anti-rheumatic drugs (DMARDs) which must include at least 3 months continuous treatment with at least 2 DMARDs, one of which must be methotrexate at a dose of at least 20 mg weekly plus one of the following: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 6 months of intensive treatment with DMARDs which, if methotrexate is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information/cannot be tolerated at a 20 mg weekly dose, must include at least 3 months continuous treatment with at least 2 of the following DMARDs: (i) hydroxychloroquine at a dose of at least 200 mg daily; (ii) leflunomide at a dose of at least 10 mg daily; (iii) sulfasalazine at a dose of at least 2 g daily; OR
- Patient must have failed, in the 24 months immediately prior to the date of the application, to achieve an adequate response to a trial of at least 3 months of continuous treatment with a DMARD where 2 of: (i) hydroxychloroquine, (ii) leflunomide, (iii) sulfasalazine, are contraindicated according to the relevant TGA-approved Product Information/cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to methotrexate: the remaining tolerated DMARD must be trialled at a minimum dose as mentioned above; OR
- Patient must have a contraindication/severe intolerance to each of: (i) methotrexate, (ii) hydroxychloroquine, (iii) leflunomide, (iv) sulfasalazine; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

If methotrexate is contraindicated according to the TGA-approved product information or cannot be tolerated at a 20 mg weekly dose, the application must include details of the contraindication or intolerance including severity to methotrexate. The maximum tolerated dose of methotrexate must be documented in the application, if applicable.

The application must include details of the DMARDs trialled, their doses and duration of treatment, and all relevant contraindications and/or intolerances including severity.

The requirement to trial at least 2 DMARDs for periods of at least 3 months each can be met using single agents sequentially or by using one or more combinations of DMARDs, however the time on treatment must be at least 6 months.

If the requirement to trial 6 months of intensive DMARD therapy with at least 2 DMARDs cannot be met because of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to all of the DMARDs specified above, details of the contraindication or intolerance including severity and dose for each DMARD must be provided in the authority application.

The following criteria indicate failure to achieve an adequate response to DMARD treatment and must be demonstrated in all patients at the time of the initial application:

an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour and/or a C-reactive protein (CRP) level greater than 15 mg per L; AND either

(a) a total active joint count of at least 20 active (swollen and tender) joints; or

(b) at least 4 active joints from the following list of major joints:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

The joint count and ESR and/or CRP must be determined at the completion of the 6 month intensive DMARD trial, but prior to ceasing DMARD therapy. All measures must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An assessment of a patient's response to this initial course of treatment must be conducted following a minimum of 12 weeks of therapy and no later than 4 weeks prior the completion of this course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months)

#### **Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have received prior PBS-subsidised treatment with a biological medicine under the paediatric Severe active juvenile idiopathic arthritis/Systemic juvenile idiopathic arthritis indication, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**



- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have received PBS-subsidised treatment for paediatric Severe active juvenile idiopathic arthritis or Systemic juvenile idiopathic arthritis where the condition has progressed to Rheumatoid arthritis may receive treatment through this restriction using existing baseline scores.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

An application for a patient who is either changing treatment from another biological medicine to this drug or recommencing therapy with this drug after a treatment break of less than 24 months, must be accompanied with details of the evidence of a response to the patient's most recent course of PBS-subsidised biological medicine, within the timeframes specified below.

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

A patient who has demonstrated a response to a course of rituximab must have a PBS-subsidised biological therapy treatment-free period of at least 22 weeks, immediately following the second infusion, before swapping to an alternate biological medicine.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months)

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 24 months or more from the most recent PBS-subsidised biological medicine for this condition, **AND**
- Patient must not have failed to respond to previous PBS-subsidised treatment with this drug for this condition, **AND**

- Patient must not have already failed/ceased to respond to PBS-subsidised biological medicine treatment for this condition 5 times, **AND**
- The condition must have an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour; OR
- The condition must have a C-reactive protein (CRP) level greater than 15 mg per L, **AND**
- The condition must have either: (a) a total active joint count of at least 20 active (swollen and tender) joints; (b) at least 4 active major joints, **AND**
- Patient must not receive more than 16 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

Major joints are defined as (i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or (ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

All measures of joint count and ESR and/or CRP must be no more than 4 weeks old at the time of initial application.

If the requirement to demonstrate an elevated ESR or CRP cannot be met, the application must state the reasons why this criterion cannot be satisfied. Treatment with prednisolone dosed at 7.5 mg or higher daily (or equivalent) or a parenteral steroid within the past month (intramuscular or intravenous methylprednisolone or equivalent) is an acceptable reason.

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 3 repeats will be authorised.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

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HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 24 months) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 24 months) to complete 16 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

An adequate response to treatment is defined as:

an ESR no greater than 25 mm per hour or a CRP level no greater than 15 mg per L or either marker reduced by at least 20% from baseline;

AND either of the following:

(a) a reduction in the total active (swollen and tender) joint count by at least 50% from baseline, where baseline is at least 20 active joints; or

(b) a reduction in the number of the following active joints, from at least 4, by at least 50%:

(i) elbow, wrist, knee and/or ankle (assessed as swollen and tender); and/or

(ii) shoulder and/or hip (assessed as pain in passive movement and restriction of passive movement, where pain and limitation of movement are due to active disease and not irreversible damage such as joint destruction or bony overgrowth).

Where the baseline active joint count is based on total active joints (i.e. more than 20 active joints), response must be determined according to the reduction in the total number of active joints. Where the baseline is determined on total number of major joints, the response must be determined on the total number of major joints. If only an ESR or CRP level is provided with the initial application, the same marker must be used to determine response.

At the time of the authority application, medical practitioners should request the appropriate number of vials of appropriate strength to provide sufficient drug, based on the weight of the patient, for a single infusion at a dose of 8 mg per kg. A separate authority prescription form must be completed for each strength requested.

Up to a maximum of 5 repeats will be authorised.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

An application for the continuing treatment must be accompanied with the assessment of response conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from cessation of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient has either failed or ceased to respond to a PBS-subsidised biological medicine for this condition 5 times, they will not be eligible to receive further PBS-subsidised treatment with a biological medicine for this condition.

If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Authority required**

Severe active rheumatoid arthritis

Treatment Phase: First continuing treatment - balance of supply

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist with expertise in the management of rheumatoid arthritis.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the first continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**tocilizumab 200 mg/10 mL injection, 10 mL vial**

9658H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	203.73	Actemra [RO]

**tocilizumab 400 mg/20 mL injection, 20 mL vial**

9659J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	405.39	Actemra [RO]

**tocilizumab 80 mg/4 mL injection, 4 mL vial**

9657G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	82.19	Actemra [RO]

▪ **USTEKINUMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Population criteria:**

- Patient must be aged 18 years or older.

### **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

- (a) patient must have evidence of intestinal inflammation;
- (b) patient must be assessed clinically as being in a high faecal output state;
- (c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 1 month following cessation of the most recent prior treatment

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Department of Human Services website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

(a) two completed authority prescription forms; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of biological medicine therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and submitted to the Department of Human Services no later than 4 weeks from the date of completion of treatment.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

**AND**

- The treatment must not exceed a total of 2 doses to be administered at weeks 0 and 8 under this restriction.

**Population criteria:**

- Patient must be aged 18 years or older.

Applications for authorisation must be made in writing and must include:

- (a) two completed authority prescription forms; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
  - (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats.

A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

An assessment of a patient's response to an initial course of treatment must be conducted following a minimum of 12 weeks of therapy. An application for the continuing treatment must be accompanied with the assessment of response and submitted to the Department of Human Services no later than 4 weeks from the date of completion of the most recent course of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Where the response assessment is not submitted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Increase in the maximum quantity or number of units up to 4 may be authorised for the purpose of weight-based loading dose.

### ustekinumab 130 mg/26 mL injection, 26 mL vial

11182M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*12000.00	Stelara [JC]

## ■ USTEKINUMAB

### **Note** TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)



**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:
  - (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and
  - (ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the toxicities, including severity, which will be accepted where one is claimed.

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and  
 (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:  
 (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and  
 (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

#### **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score), **AND**
- The treatment must not exceed a single dose to be administered at week 0 under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and  
 (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice), which includes:  
 (i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and  
 (ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A maximum of 16 weeks of treatment with this drug will be approved under this criterion.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4

vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for the subsequent first dose, containing a quantity of 1 pre-filled syringe of 90 mg and no repeats.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**ustekinumab 130 mg/26 mL injection, 26 mL vial**

13272M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*12000.00	Stelara [JC]

▪ **USTEKINUMAB**

**Note TREATMENT OF COMPLEX REFRACTORY FISTULISING CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for patients with complex refractory fistulising Crohn disease. Where the term 'biological medicine' appears in the following notes and restrictions, it refers to adalimumab, infliximab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the PBS-subsidised biological medicines for this condition at any one time.

From 1 April 2011, under the PBS, all patients will be able to commence a treatment cycle where they may trial PBS-subsidised adalimumab, infliximab or ustekinumab without having to experience a disease flare when swapping to the alternate agent. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with adalimumab, infliximab or ustekinumab while they continue to show a response to therapy.

A patient who received PBS-subsidised adalimumab, infliximab or ustekinumab treatment prior to 1 April 2011 is considered to have started their treatment cycle as of 1 April 2011.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised adalimumab, infliximab or ustekinumab more than twice.

Once a patient has either failed or ceased to respond to treatment for this condition 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy for this condition before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised adalimumab, infliximab or ustekinumab treatment in the most recent cycle to the date of the first application for initial treatment with adalimumab, infliximab or ustekinumab under the new treatment cycle.

A patient who has failed fewer than 3 trials of biological medicine therapy in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed 3 trials or fewer of biological medicine therapy in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised adalimumab, infliximab or ustekinumab therapy after 1 April 2011.

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised adalimumab, infliximab or ustekinumab therapy in this treatment cycle and wishes to commence such therapy (Initial 1- new patient or recommencement of treatment after a break in biological medicine of more than 5 years); or

(ii) a patient has received prior PBS-subsidised (initial or continuing) adalimumab, infliximab or ustekinumab therapy and wishes to trial an alternate agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to recommence treatment with adalimumab, infliximab or ustekinumab following a break in PBS-subsidised therapy with that agent (Initial 2 - change or recommencement of treatment after a break in biological medicine of less than 5 years).

Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and ustekinumab and 14 weeks of therapy for infliximab.

From 1 April 2011, a patient must be assessed for response to any course of initial PBS-subsidised treatment following a minimum of 12 weeks of therapy for adalimumab and ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab, and this assessment must be conducted no later than 4 weeks from the date that course was ceased.

Where a response assessment is not conducted within these timeframes, the patient will be deemed to have failed to respond to treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(b) Continuing treatment.

Following the completion of an initial treatment course with a biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment under the Initial 1, or Initial 2 treatment restrictions.

For the second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(2) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap if eligible to the alternate biological medicine within the same treatment cycle.

A patient may trial the alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with adalimumab, infliximab or ustekinumab at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug two times within the same

treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment within the timeframes specified in the relevant restriction.

A patient who is not able to complete an initial treatment course for a biological medicine will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

(3) Baseline measurements to determine response.

A response to treatment is to be determined by comparison of current disease activity measurements relative to the baseline measurements submitted with the first authority application for adalimumab, infliximab or ustekinumab. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and the eligibility for continuing treatment must be assessed according to these revised baseline measurements.

(4) Re commencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to recommence treatment following a break in PBS-subsidised biological medicine therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity.

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

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

**Note** Special Pricing Arrangements apply.

## **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years)

### **Clinical criteria:**

- Patient must have confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have an externally draining enterocutaneous or rectovaginal fistula.

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Applications for authorisation must be made in writing and must include:

(1) two completed authority prescription forms; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes a completed current Fistula Assessment Form including the date of assessment of the patient's condition of no more than 4 weeks old at the time of application.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.

An assessment of a patient's response to this initial course of treatment must be conducted between 8 and 16 weeks of therapy.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**

- Patient must not have failed PBS-subsidised therapy with this drug for this condition more than once in the current treatment cycle.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied with the assessment of response, conducted between 8 and 16 weeks of therapy and no later than 4 weeks from cessation of the most recent course of biological medicine. It is recommended that an application for the continuing treatment be submitted no later than 4 weeks from the date of completion of the most recent course of treatment. This is to ensure treatment continuity for those who meet the continuing restriction.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Applications for authorisation must be made in writing and must include:

- (1) two completed authority prescription forms; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) a completed current Fistula Assessment Form including the date of assessment of the patient's condition; and
  - (ii) details of prior biological medicine treatment including details of date and duration of treatment.

Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 1 vial or pre-filled syringe of 90 mg and no repeats.

The most recent fistula assessment must be no more than 4 weeks old at the time of application.

A maximum quantity of a weight-based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16-week course of this drug will be authorised

Where fewer than 6 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Complex refractory Fistulising Crohn disease

Treatment Phase: Initial 1 (new patient or recommencement of treatment after a break in biological medicine of more than 5 years), Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) - balance of supply

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient or patient recommencing treatment after a break of 5 years or more) restriction to complete 16 weeks treatment; OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break of less than 5 years) restriction to complete 16 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 16 weeks treatment available under the above restrictions.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**ustekinumab 130 mg/26 mL injection, 26 mL vial**

13781H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*12000.00	Stelara [JC]

*Calcineurin inhibitors*

▪ **CICLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**6628**

Management of transplant rejection

**Clinical criteria:**

- The treatment must be used by organ or tissue transplant recipients.

**ciclosporin 50 mg/mL injection, 10 x 1 mL ampoules**

5631J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	54.10	Sandimmun [NV]

▪ **CICLOSPORIN**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**6643**

Management of transplant rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have had an organ or tissue transplantation, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

**Authority required (STREAMLINED)**

**6660**

Severe atopic dermatitis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a clinical immunologist.

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies.

**Authority required (STREAMLINED)**

**15360**

Severe psoriasis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must be ineffective to other systemic therapies; OR
- The condition must be inappropriate for other systemic therapies, **AND**
- The condition must have caused significant interference with quality of life.

**Treatment criteria:**

- Must be treated by a medical practitioner who is either: (i) a dermatologist, (ii) a rheumatologist, (iii) general physician; OR
- Must be treated by a medical practitioner in consultation with one of the above specialist types who is either an accredited: (i) dermatology registrar, (ii) rheumatology registrar.

For patients who do not demonstrate an adequate response to ciclosporin, a Psoriasis Area and Severity Index (PASI) assessment must be completed, preferably while on treatment, but no longer than 4 weeks following the cessation of treatment. This assessment will be required for patients who transition to 'biological medicines' for the treatment of 'severe chronic plaque psoriasis'.

This assessment must be documented in the patient's medical records.

**Authority required (STREAMLINED)**

**6631**

Nephrotic syndrome

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- Patient must have failed prior treatment with steroids and cytostatic drugs; OR
- Patient must be intolerant to treatment with steroids and cytostatic drugs; OR
- The condition must be considered inappropriate for treatment with steroids and cytostatic drugs, **AND**
- Patient must not have renal impairment.

**Treatment criteria:**

- Must be treated by a nephrologist.

**Authority required (STREAMLINED)**

**6638**

Severe active rheumatoid arthritis

Treatment Phase: Management (initiation, stabilisation and review of therapy)

**Clinical criteria:**

- The condition must have been ineffective to prior treatment with classical slow-acting anti-rheumatic agents (including methotrexate); OR
- The condition must be considered inappropriate for treatment with slow-acting anti-rheumatic agents (including methotrexate).

**Treatment criteria:**

- Must be treated by a rheumatologist; OR
- Must be treated by a clinical immunologist.

**ciclosporin 100 mg/mL oral liquid, 50 mL**

5633L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	4	5	..	*1263.16	Neoral [NV]	

**ciclosporin 25 mg capsule, 30**

5634M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*88.16	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 25 [NV]

**ciclosporin 50 mg capsule, 30**

5635N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*183.48	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 50 [NV]

**ciclosporin 10 mg capsule, 60**

5632K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	2	5	..	*74.40	Neoral 10 [NV]	

**ciclosporin 100 mg capsule, 30**

5636P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*373.80	<sup>a</sup> APO-Ciclosporin [TX] <sup>a</sup> Cyclosporin Sandoz [NM]	<sup>a</sup> CICLOSPORIN-WGR [WG] <sup>a</sup> Neoral 100 [NV]

▪ **TACROLIMUS**

**Caution** Careful monitoring of patients is mandatory.

**Authority required (STREAMLINED)**

**5569**

Management of rejection in patients following organ or tissue transplantation

**Clinical criteria:**

- The treatment must be under the supervision and direction of a transplant unit, **AND**
- The treatment must include initiation, stabilisation, and review of therapy as required.

**tacrolimus 500 microgram capsule, 100**

9558C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*102.96	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 0.5 [CR] <sup>a</sup> Tacrograf [RW]

**tacrolimus 500 microgram modified release capsule, 30**

9664P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*75.04	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 1 mg capsule, 100**

9560E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*205.92	<sup>a</sup> Pacrolim [AF] <sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]	<sup>a</sup> Pharmacor Tacrolimus 1 [CR] <sup>a</sup> Tacrograf [RW]

**tacrolimus 3 mg modified release capsule, 50**

11907Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	3	..	*658.20	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 1 mg modified release capsule, 60**

9665Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*123.56	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 5 mg capsule, 50**

9561F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*514.56	<sup>a</sup> Pharmacor Tacrolimus 5 [CR] <sup>a</sup> Tacrograf [RW]	<sup>a</sup> Prograf [LL] <sup>a</sup> Tacrolimus Sandoz [SZ]

**tacrolimus 5 mg modified release capsule, 30**

9666R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*750.44	<sup>a</sup> ADVAGRAF XL [LQ]	<sup>a</sup> Tacrolimus XR Sandoz [SZ]

**tacrolimus 750 microgram capsule, 100**

10859M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	
	2	5	..	*196.16	Tacrolimus Sandoz [SZ]	

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

### tacrolimus 2 mg capsule, 100

10860N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*469.30	Tacrolimus Sandoz [SZ]

#### Monoclonal antibodies

#### ■ ALEMTUZUMAB

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

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

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

#### Authority required (STREAMLINED)

**6847**

Multiple sclerosis

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- Patient must not receive more than one PBS-subsidised treatment per year, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

#### **Treatment criteria:**

- Must be treated by a neurologist.

### alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10232M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	..	..	*30849.27	Lemtrada [GZ]

#### ■ ALEMTUZUMAB

**Note** Neurologists prescribing PBS-subsidised alemtuzumab must be registered with the Lemtrada monitoring program.

**Note** Special Pricing Arrangements apply.

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

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

#### Authority required (STREAMLINED)

**7714**

Multiple sclerosis

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

#### **Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

### alemtuzumab 12 mg/1.2 mL injection, 1.2 mL vial

10228H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	..	..	*51415.45	Lemtrada [GZ]

#### ■ ANIFROLUMAB

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

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

**Note** Special Pricing Arrangements apply.

**Note** SLEDAI-2K can be accessed via Gladman 2002 J. Rheumatol. 29 (2) 288-291 or from AstraZeneca Medical Information on 1800 805 342.

#### Authority required

Systemic lupus erythematosus

Treatment Phase: Initial treatment

#### **Clinical criteria:**



- Patient must have a confirmed and documented diagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019, **AND**
- Patient must have persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points, **AND**
- Patient must be currently receiving hydroxychloroquine, with treatment received for at least 12 weeks, unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must be currently receiving immunosuppressant medication, with treatment received for at least 12 weeks, with either: (i) minimum dose of methotrexate 20 mg per week, (ii) azathioprine 100 mg per day, (iii) mycophenolate 1,000 mg per day unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must be currently receiving prednisolone or equivalent of at least 7.5 mg per day, with treatment received for at least 4 weeks, unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must not have either: (i) severe active lupus nephritis, (ii) severe active central nervous system systemic lupus erythematosus.

**Treatment criteria:**

- Must be treated by a specialist physician experienced in the management of this condition.

If prednisolone or equivalent is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated of at least 7.5 mg per day, the patient must have received at least 12 weeks of continuous treatment with each of at least 2 of the following: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day.

Where two of: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; or (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to prednisolone or equivalent: at least one of the remaining tolerated therapies must be trialled at a minimum dose as mentioned above.

If the patient has a contraindication/severe intolerance to each of: (i) prednisolone or equivalent of at least 7.5 mg per day; (ii) hydroxychloroquine; (iii) methotrexate at a dose of at least 20 mg per week; (iv) azathioprine at a dose of at least 100 mg per day; (v) mycophenolate at a dose of at least 1,000 mg per day; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application.

The authority application must be made in writing via HPOS form upload or mail and must include:

- (a) details of the ACR/EULAR SLE Classification Criteria 2019 confirming diagnosis of SLE;
- (b) details (date and score) of the completed SLEDAI-2K score sheet;
- (c) details of current systemic therapy used (dosage, date of commencement and duration of therapy including prior anifrolumab use);
- (d) details of contraindication/intolerances to prior therapies (drug name, the degree of toxicity and dose).

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Systemic lupus erythematosus

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 July 2024, **AND**
- Patient must have had a confirmed and documented diagnosis of systemic lupus erythematosus (SLE) according to the American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) SLE Classification Criteria 2019 prior to commencing therapy with this drug for this condition, **AND**
- Patient must have had persistent disease activity as supported by a SLE Disease Activity Index 2000 (SLEDAI-2K) score of at least 10 points prior to commencing therapy with this drug for this condition, **AND**
- Patient must have been receiving hydroxychloroquine for at least 12 weeks prior to commencing therapy with this drug for this condition, **AND**
- Patient must have been receiving immunosuppressant medication for at least 12 weeks with either (i) minimum dose of methotrexate 20 mg per week (ii) azathioprine 100 mg per day (iii) mycophenolate 1,000 mg per day, prior to commencing therapy with this drug for this condition unless contraindicated/intolerant necessitating treatment withdrawal, **AND**
- Patient must have been receiving prednisolone or equivalent of at least 7.5 mg per day for at least 4 weeks prior to commencing therapy with this drug for this condition unless contraindicated/intolerant necessitating treatment withdrawal, **AND**

**AND**

- Patient must not have either: (i) severe active lupus nephritis, (ii) severe active central nervous system systemic lupus erythematosus.

### Treatment criteria:

- Must be treated by a specialist physician experienced in the management of this condition.

If prednisolone or equivalent is contraindicated according to the Therapeutic Goods Administration (TGA)-approved Product Information or cannot be tolerated at least 7.5 mg per day, the patient must have received at least 12 weeks of continuous treatment with each of at least 2 of the following: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day.

Where two of: (i) hydroxychloroquine; (ii) methotrexate at a dose of at least 20 mg per week; or (iii) azathioprine at a dose of at least 100 mg per day; (iv) mycophenolate at a dose of at least 1,000 mg per day, are either contraindicated according to the relevant TGA-approved Product Information or cannot be tolerated at the doses specified above in addition to having a contraindication or intolerance to prednisolone or equivalent: at least one of the remaining tolerated therapies must be trialled at a minimum dose as mentioned above.

If the patient has a contraindication/severe intolerance to each of: (i) prednisolone or equivalent of at least 7.5 mg per day; (ii) hydroxychloroquine; (iii) methotrexate at a dose of at least 20 mg per week; (iv) azathioprine at a dose of at least 100 mg per day; (v) mycophenolate at a dose of at least 1,000 mg per day; in such cases, provide details for each of the contraindications/severe intolerances claimed in the authority application.

The authority application must be made in writing via HPOS form upload or mail and must include:

- (a) details of the ACR/EULAR SLE Classification Criteria 2019 confirming diagnosis of SLE;
- (b) details (date and score) of the completed SLEDAI-2K score sheet;
- (c) details of current systemic therapy used (dosage, date of commencement and duration of therapy including prior anifrolumab use);
- (d) details of contraindication/intolerances to prior therapies (drug name, the degree of toxicity and dose).

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Systemic lupus erythematosus

Treatment Phase: Continuing or recommencement of treatment (within 12 months of a treatment break)

### **Clinical criteria:**

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must be responding to treatment if they have received less than 12 months of treatment with this drug for this condition; OR
- Patient must have attained a Lupus Low Disease Activity State (LLDAS) and maintained this state while on treatment.

### **Treatment criteria:**

- Must be treated by a specialist physician experienced in the management of this condition.

Lupus Low Disease Activity State (LLDAS) is defined as:

- (a) Total SLEDAI-2K of not greater than 4, with no major activity in major organ systems (renal, central nervous system (CNS), cardiopulmonary, vasculitis, fever); and
- (b) No new features of lupus disease activity compared with the previous assessment, and
- (c) Physician Global Assessment (PGA) of not greater than 1, and
- (d) Current prednisolone (or equivalent) dose of not greater than 7.5 mg daily, and
- (e) Well tolerated standard maintenance doses of anti-malarial and immunosuppressive drugs are allowed.

Where retreatment with anifrolumab after a break in PBS-subsidised treatment with anifrolumab is being sought, the date of cessation of the previous treatment course with anifrolumab must be included in the application. Recommencement of treatment with anifrolumab for severe SLE is within 12 months from the date that treatment was ceased.

**Note** PGA can be accessed via Petri 2005 N Engl J Med 353: 2550-8.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**anifrolumab 300 mg/2 mL injection, 2 mL vial**

14195D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1448.00	Saphnelo [AP]

▪ **NATALIZUMAB**

**Caution** Progressive multifocal leukoencephalopathy has been reported with this drug.

**Authority required (STREAMLINED)**

**13718**

Clinically definite relapsing-remitting multiple sclerosis

**Treatment criteria:**

- Must be treated by a neurologist.

**Clinical criteria:**

- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support), **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- The condition must be confirmed by magnetic resonance imaging of the brain and/or spinal cord; OR
- Patient must be deemed unsuitable for magnetic resonance imaging due to the risk of physical (not psychological) injury to the patient.

The date of the magnetic resonance imaging scan must be included in the patient's medical notes, unless written certification is provided, in the patient's medical notes, by a radiologist that an MRI scan is contraindicated because of the risk of physical (not psychological) injury to the patient.

Treatment with this drug must cease if there is continuing progression of disability whilst the patient is being treated with this drug.

For continued treatment the patient must demonstrate compliance with, and an ability to tolerate, this drug.

**natalizumab 300 mg/15 mL injection, 15 mL vial**

9505G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	937.30	Tysabri [BD]

**natalizumab 150 mg/mL injection, 2 x 1 mL syringes**

13825P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	937.30	Tysabri [BD]

▪ **OCRELIZUMAB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**7699**

Multiple sclerosis

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by magnetic resonance imaging of the brain and/or spinal cord; OR
- The condition must be diagnosed as clinically definite relapsing-remitting multiple sclerosis by accompanying written certification provided by a radiologist that a magnetic resonance imaging scan is contraindicated because of the risk of physical (not psychological) injury to the patient, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have experienced at least 2 documented attacks of neurological dysfunction, believed to be due to multiple sclerosis, in the preceding 2 years of commencing a PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must be ambulatory (without assistance or support).

**Treatment criteria:**

- Must be treated by a neurologist.

Where applicable, the date of the magnetic resonance imaging scan must be recorded in the patient's medical records.

**Authority required (STREAMLINED)**

**7386**

Multiple sclerosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not show continuing progression of disability while on treatment with this drug, **AND**
- The treatment must be the sole PBS-subsidised disease modifying therapy for this condition, **AND**
- Patient must have demonstrated compliance with, and an ability to tolerate this therapy.

**Treatment criteria:**

- Must be treated by a neurologist.

**ocrelizumab 300 mg/10 mL injection, 10 mL vial**

11242Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*16656.36	Ocrevus [RO]

▪ **VEDOLIZUMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Special Pricing Arrangements apply.

**Note** Patient must be assessed as having an inadequate response to the drug after completing an initial infusion regimen at 0, 2, and 6 weeks and prior to 10 weeks.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 4 (additional dose at week 10)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition in this treatment cycle, **AND**
- Patient must have received 3 doses of initial treatment under either (i) initial 1, (ii) initial 2, (iii) initial 3, **AND**
- Patient must not have achieved an adequate response to this drug after a total of 3 doses of initial treatment under either (i) initial 1, (ii) initial 2, (iii) initial 3 under this restriction, **AND**
- The treatment must not exceed a total of 4 doses to be administered at weeks 0, 2, 6 and 10 under the initial treatment phase.

**Population criteria:**

- Patient must be at least 18 years of age.

A maximum quantity and number of repeats to provide for an additional dose of this drug consisting of one vial of 300 mg, with one dose to be administered at week 10, will be authorised.

The assessment of the patient's response to the initial course of treatment must be conducted prior to 10 weeks and a second assessment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

An adequate response to this drug defined as:

a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; or

(a) an improvement of intestinal inflammation as demonstrated by:

(i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or

(ii) faeces: normalisation of lactoferrin or calprotectin level; or

(iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or

(b) reversal of high faecal output state; or

(c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient.

**vedolizumab 300 mg injection, 1 vial**

14630B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2949.93	Entyvio [TK]

▪ **VEDOLIZUMAB**

**Note TREATMENT OF ADULT PATIENTS WITH MODERATE TO SEVERE ULCERATIVE COLITIS**

The following information applies to Pharmaceutical Benefits Scheme (PBS) benefits for the indication of moderate to severe ulcerative colitis (MSUC). Patients are eligible for one PBS-subsidised drug treatment indicated for MSUC at any one time.

Where the term 'biological medicine' appears in this note and restrictions, it refers to any PBS benefit indicated for MSUC. Some benefits are not biological medicines, but are small molecules. However, for practical purposes, these benefits are included within the term 'biological medicine'.

From 1 July 2021, under the PBS, all adult patients will be able to commence a treatment cycle where they may trial PBS-subsidised biological medicine without having to experience a disease flare when swapping to one of the alternate agents. Under these arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a PBS-subsidised biological medicine while they continue to show a response to therapy.

A patient who received PBS-subsidised biological medicine treatment prior to 1 July 2021 is considered to have started their first cycle as of 1 July 2021. Within the same treatment cycle, the same biological medicine cannot be trialled twice. Where 3 biological medicines have failed to provide the patient with an adequate response a treatment cycle is considered complete. There must be a 5-year break in PBS-subsidised therapy before starting the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for Initial treatment with a PBS-subsidised biological medicine under the new treatment cycle.

A serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

Selecting the correct treatment phase listing when applying for authority approval:

(1) Initial treatment.

Apply under an Initial 1 treatment listing where the patient has never received a biological medicine.

(2) Continuing treatment.

Under no circumstance is Continuing treatment to precede Initial treatment. An authority application for Continuing treatment is not to be made on the same day as Initial treatment.

(3) Changing therapy.

Apply under an Initial 2 treatment listing. The indices of disease severity (i.e. Mayo clinic score or partial Mayo clinic score), or the prior corticosteroid therapy and immunosuppressive therapy will not need to be restated. A patient may trial an alternate biological medicine treatment at any time, regardless of whether they are receiving therapy (initial or continuing) at the time of the application. However, they cannot change to a particular biological medicine if they have failed to respond to prior treatment with that drug once within the same treatment cycle. A response assessment to the preceding supply of biological medicine must accompany this Initial 2 treatment authority application.

(4) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

Apply under an Initial 3 treatment listing. Prior corticosteroid and immunosuppressive therapies need not be re-trialled.

(5) Balance of supply.

Where the full number of repeat prescriptions have not been requested under any initial or continuing listing, apply for the balance of the supply of the repeats under any treatment phase listing containing the words "balance of supply".

**Note** Special Pricing Arrangements apply.

## **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have failed to achieve an adequate response to a 5-aminosalicylate oral preparation in a standard dose for induction of remission for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal, **AND**
- Patient must have failed to achieve an adequate response to azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months or have intolerance necessitating permanent treatment withdrawal; OR
- Patient must have failed to achieve an adequate response to a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period or have intolerance necessitating permanent treatment withdrawal, and followed by a failure to achieve an adequate response to 3 or more consecutive months of treatment of an appropriately dosed thiopurine agent, **AND**
- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

### **Population criteria:**

- Patient must be at least 18 years of age.

Application for authorisation of initial treatment must be in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy].

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, details must be provided at the time of application.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle.

**Population criteria:**

- Patient must be at least 18 years of age.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.

Authority approval for sufficient therapy to complete a maximum of 3 initial doses of treatment may be requested by telephone by contacting the Department of Human Services.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient who fails to demonstrate a response to treatment with this drug under this restriction will not be eligible to receive further PBS-subsidised treatment with this drug in this treatment cycle. A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**

- Patient must have a Mayo clinic score greater than or equal to 6; OR
- Patient must have a partial Mayo clinic score greater than or equal to 6, provided the rectal bleeding and stool frequency subscores are both greater than or equal to 2 (endoscopy subscore is not required for a partial Mayo clinic score).

**Population criteria:**

- Patient must be at least 18 years of age.

Application for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Ulcerative Colitis PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition; and

(ii) the details of prior biological medicine treatment including the details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 4 weeks following cessation of the most recent prior conventional treatment.

The most recent Mayo clinic or partial Mayo clinic score must be no more than 4 weeks old at the time of application.

A partial Mayo clinic assessment of the patient's response to this initial course of treatment must be following a minimum of 12 weeks of treatment for adalimumab and up to 12 weeks after the first dose (6 weeks following the third dose) for golimumab, infliximab and vedolizumab so that there is adequate time for a response to be demonstrated.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under either Initial 1, Initial 2, Initial 3 or continuing treatment restrictions, an assessment of a patient's response must have been conducted following a minimum of 12 weeks of therapy and submitted no later than 4 weeks from the date of completion of treatment.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

Details of the accepted toxicities including severity can be found on the Services Australia website.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must have demonstrated or sustained an adequate response to treatment by having a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 while receiving treatment with this drug.

**Population criteria:**

- Patient must be at least 18 years of age.

Patients who have failed to maintain a partial Mayo clinic score less than or equal to 2, with no subscore greater than 1 with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide for a single infusion of 300 mg per dose.

Up to a maximum of 2 repeats will be authorised.



An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Moderate to severe ulcerative colitis

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 3 doses therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**vedolizumab 300 mg injection, 1 vial**

10384M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2949.93	Entyvio [TK]

▪ **VEDOLIZUMAB**

**Note SEVERE CROHN DISEASE - TREATMENT PHASES AND CYCLES**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of benefits that contain the words: 'severe Crohn disease' in the stated PBS indication. Some of these benefits are not biological medicines, but are small molecules (e.g. a Janus-kinase inhibitor). Where the term 'biological medicine' appears in the restriction, it includes such benefits for PBS administrative purposes.

A patient is eligible for PBS-subsidised treatment with only one PBS-subsidised biological medicine at any one time.

Treatment cycle:

A treatment cycle begins when an authority application is approved under an Initial 1 or Initial 3 type restriction. Once commenced, where biological medicine fails to provide the patient with an adequate response on 3 occasions, the current treatment cycle ends and there must be an absence of PBS-subsidy for a period of 5 years. The 5 year break is measured from the date of the last approval for PBS-subsidised biological medicine treatment in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new treatment cycle.

An exception to this 5 year break clause applies where:

- (i) since the commencement of the break, an additional biological medicine has since become PBS-listed with a different pharmacological mechanism of action (i.e. the newly listed biological medicine) relative to those available on the PBS at the time of commencing the 5 year break; and
- (ii) the patient has never been prescribed the newly listed biological medicine; and
- (iii) the prescribed biological medicine is the newly listed biological medicine.

Prescribing of the newly listed biological medicine is to occur through the 'Initial 2' treatment phase listing and the patient will not be in a new treatment cycle (i.e. where this newly listed biological medicine fails to provide an adequate response, the current treatment cycle ends and there must be an absence of PBS-subsidised biological medicine for a period of 5 years unless the exception outlined above is triggered again).

Within the same treatment cycle, the same PBS-subsidised biological medicine cannot continue to be subsidised where it has resulted in an inadequate response. An inadequate response is one which does not meet the minimum improvements in disease measures stated in the Continuing treatment restriction. A serious adverse reaction leading to treatment discontinuation will be exempted from being counted as an inadequate response.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

Treatment phases:

(a) Initial 1

Apply through this treatment phase where the patient has never been treated with PBS-subsidised biological medicine for this indication.

(b) Initial 2

Apply through this treatment phase where the prescribed treatment is changing (other than dose/form), or, where there has been a break in therapy of less than 5 years and treatment is resuming; authority applications through this treatment phase do not require prior response to conventional therapies to be re-established and do not require baseline disease activity to be re-demonstrated. An assessment of response to the preceding supply must be provided - where it is not, it will be assumed that the preceding supply provided an inadequate response.

(c) Initial 3

Apply through this treatment phase where treatment is resuming after an absence of PBS-subsidy for at least 5 years; authority applications through this treatment phase do not require a re-trial of conventional therapies.

(d) Continuing treatment

Apply through this treatment phase where an adequate response to the preceding supply is observed (or where the dose is increasing where multiple strengths exist). It is recommended that a patient be reviewed in the 4 weeks prior to exhausting the current supply to ensure uninterrupted supply. Continuing treatment authority applications are not to be made on the same day as Initial treatment authority applications.

(e) Balance of supply

Apply through this type of treatment phase only where the benefit was not requested in the full amount available in the preceding supply - this may be because the maximum quantity was not prescribed and/or the full number of repeat prescriptions was not prescribed. The intent of this treatment phase listing is to: (i) provide the balance of what could have been obtained had the full quantity and number of repeats been prescribed in the preceding authority application, (ii) allow further time for an adequate response to treatment to be demonstrated where it may not have already, and (iii) provide more immediate access to PBS-subsidy via a telephone/online authority application relative to an 'in-writing only' application where the preceding supply was obtained through such.

**Note** Special Pricing Arrangements apply.

## **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 1 (new patient)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period, **AND**
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with azathioprine at a dose of at least 2 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more consecutive months; OR
- Patient must have failed to achieve adequate response to prior systemic immunosuppressive therapy with methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as evidence of failure to achieve an adequate response to prior systemic therapy; OR
- Patient must have short gut syndrome with diagnostic imaging or surgical evidence, or have had an ileostomy or colostomy; and must have evidence of intestinal inflammation; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below; OR
- Patient must have extensive intestinal inflammation affecting more than 50 cm of the small intestine as evidenced by radiological imaging; and must have a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; and must have evidence of failure to achieve an adequate response to prior systemic therapy as specified below.

### **Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and

(iv) the date of the most recent clinical assessment.

Evidence of failure to achieve an adequate response to prior therapy must include at least one of the following:

(a) patient must have evidence of intestinal inflammation;

(b) patient must be assessed clinically as being in a high faecal output state;

(c) patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

All assessments, pathology tests and diagnostic imaging studies must be made within 4 weeks of the date of application and should be performed preferably whilst still on conventional treatment, but no longer than 4 weeks following cessation of the most recent prior treatment.

If treatment with any of the specified prior conventional drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, details of this toxicity must be provided at the time of application.

Details of the accepted toxicities including severity can be found on the Services Australia website.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle. Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition during the current treatment cycle, **AND**
- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form, which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of assessment of the patient's condition if relevant; or

(ii) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and

(iii) the date of clinical assessment; and

(iv) the details of prior biological medicine treatment including the details of date and duration of treatment.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change or recommence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised biological medicine treatment, within the timeframes specified below.

Where the most recent course of PBS-subsidised biological medicine treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course following a minimum of 12 weeks of therapy for adalimumab or ustekinumab and up to 12 weeks after the first dose (6 weeks following the third dose) for infliximab and vedolizumab and this assessment must be submitted no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of biological medicine treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of biological medicine.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Severe Crohn disease

Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)

### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

### **Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition, **AND**
- Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition, **AND**
- Patient must have confirmed severe Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician, **AND**
- Patient must have a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 that is no more than 4 weeks old at the time of application; OR
- Patient must have a documented history of intestinal inflammation and have diagnostic imaging or surgical evidence of short gut syndrome if affected by the syndrome or has an ileostomy or colostomy; OR
- Patient must have a documented history and radiological evidence of intestinal inflammation if the patient has extensive small intestinal disease affecting more than 50 cm of the small intestine, together with a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220 and that is no more than 4 weeks old at the time of application, **AND**
- Patient must have evidence of intestinal inflammation; OR
- Patient must be assessed clinically as being in a high faecal output state; OR
- Patient must be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient,

### **AND**

- The treatment must not exceed a total of 3 doses to be administered at weeks 0, 2 and 6 under this restriction.

### **Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition if relevant; and
- (ii) the reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
- (iii) the date of the most recent clinical assessment.

Evidence of intestinal inflammation includes:

- (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; or
- (ii) faeces: higher than normal lactoferrin or calprotectin level; or
- (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

A maximum quantity and number of repeats to provide for an initial course of this drug consisting of one vial of 300 mg per dose, with one dose to be administered at weeks 0, 2 and 6, will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of this drug may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

The assessment of the patient's response to the initial course of treatment must be conducted following a minimum of 12 weeks of treatment and no later than 4 weeks from the cessation of that treatment course. If the response assessment is not conducted within these timeframes, the patient will be deemed to have failed this course of treatment in this treatment cycle.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Severe Crohn disease

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological medicine treatment for this condition; OR
- Patient must have received this drug in the subcutaneous form as their most recent course of PBS-subsidised biological medicine for this condition under the vedolizumab subcutaneous form continuing restriction, **AND**
- Patient must have an adequate response to this drug defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150 if assessed by CDAI or if affected by extensive small intestine disease; OR
- Patient must have an adequate response to this drug defined as (a) an improvement of intestinal inflammation as demonstrated by: (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; or (ii) faeces: normalisation of lactoferrin or calprotectin level; or (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or (b) reversal of high faecal output state; or (c) avoidance of the need for surgery or total parenteral nutrition (TPN), if affected by short gut syndrome, extensive small intestine or is an ostomy patient, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Applications for authorisation must be made in writing and must include:

(a) details of the proposed prescription; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form which includes the following:

- (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition, if relevant; or
- (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy for patients with short gut syndrome, extensive small intestine disease or an ostomy, if relevant; and
- (iii) the date of clinical assessment.

All assessments, pathology tests, and diagnostic imaging studies must be made within 1 month of the date of application. An application for the continuing treatment must be accompanied with the assessment of response following a minimum of 12 weeks of therapy with this drug and submitted no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle. Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered as a treatment failure.

A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, to provide sufficient for a single infusion of 300 mg vedolizumab per dose. Up to a maximum of 2 repeats will be authorised.

If fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete 24 weeks treatment may be requested by telephone and authorised through the Balance of Supply treatment phase PBS restriction. Under no circumstances will telephone approvals be granted for continuing authority applications, or for treatment that would otherwise extend the continuing treatment period.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Severe Crohn disease

Treatment Phase: Balance of supply

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug for this condition under the Initial 1 (new patient) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) restriction to complete the 3 doses (the initial infusion regimen at 0, 2 and 6 weeks); OR
- Patient must have received insufficient therapy with this drug for this condition under the continuing treatment restriction to complete 24 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks therapy available under Initial 1, 2 or 3 treatment; OR
- The treatment must provide no more than the balance of up to 24 weeks therapy available under Continuing treatment.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**vedolizumab 300 mg injection, 1 vial**

10390W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	2949.93	Entyvio [TK]

▪ **VEDOLIZUMAB**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Moderate to severe chronic pouchitis

Treatment Phase: Initial 1 treatment (new patient)

**Clinical criteria:**

- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis (UC) at least one year previously, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5, **AND**
- Patient must have a minimum endoscopic mPDAI sub-score of at least 2, **AND**
- Patient must have had at least 3 recurrent episodes of pouchitis within the previous year each of which was treated with at least: (i) 2 weeks of antibiotic, (ii) other prescription therapy; OR
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- The treatment must be initiated in combination with standard of care antibiotic.

The assessment of a patient's response to this initial course of treatment must be made after the third dose of vedolizumab so there is an adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14. Where a response assessment is not conducted within this timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

Application for authorisation of initial treatment must be in writing and must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:

- (i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and endoscopic mPDAI subscore; and
- (ii) details of prior drug therapy for this condition [dosage, date of commencement and duration of therapy].

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to the application.

Applications for treatment of this condition must be received within 4 weeks of the endoscopy to confirm diagnosis.

The prescriber must exclude secondary causes of pouchitis, for example:

- (a) Ischaemia;
- (b) Crohn's disease (CD) or CD of the pouch;
- (c) Irritable pouch syndrome;
- (d) Predominant cuffitis;
- (e) Pouch stricture or pouch fistula;
- (f) Active infection;
- (g) NSAIDs;
- (h) Coeliac disease.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe chronic pouchitis

Treatment Phase: Initial 2 treatment (Recommencement of treatment after a break in biological medicine)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 14 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Clinical criteria:**

- The treatment must be initiated in combination with standard of care antibiotic. The assessment of a patient's response to this initial course of treatment must be made after the third dose of vedolizumab so there is adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Application for authorisation of initial treatment must be in writing and must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the details of prior biological medicine therapy for this condition [date of commencement and duration of therapy].

The prescriber must have excluded secondary causes of pouchitis, for example:

- (a) Ischaemia;
- (b) Crohn's disease (CD) or CD of the pouch;
- (c) Irritable pouch syndrome;
- (d) Predominant cuffitis;
- (e) Pouch stricture or pouch fistula;
- (f) Active infection;
- (g) NSAIDs;
- (h) Coeliac disease.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Moderate to severe chronic pouchitis

Treatment Phase: Balance of Supply - Initial 1 treatment (new patient) and Initial 2 treatment (recommencement of treatment after a break in biological medicine)

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 treatment (new patient) restriction to complete 14 weeks of treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 treatment (recommencement of treatment after a break in biological medicine) to complete 14 weeks of treatment, **AND**
- The treatment must provide no more than the balance of up to 14 weeks treatment available under the above treatment phases.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Moderate to severe chronic pouchitis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received this drug as their most recent course of PBS-subsidised biological medicine for this condition, **AND**
- Patient must have demonstrated or sustained a partial or complete response, as determined by the treating clinician, to the most recent PBS-subsidised course of treatment with this drug for this condition.

**Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

Patients who have failed to demonstrate a partial or complete response with continuing treatment with this drug, will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

Patients are eligible to receive continuing treatment with this drug in courses of up to 24 weeks providing they continue to sustain a response.



An application for the continuing treatment must be made following the third dose with this drug and requested no later than 4 weeks from the date of completion of treatment. This will enable ongoing treatment for those who meet the continuing restriction for PBS-subsidised treatment. Where an application is not made within these timeframes, the patient will be deemed to have failed to respond to treatment with this drug

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Moderate to severe chronic pouchitis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS indication prior to 1 December 2024, **AND**
- Patient must be receiving treatment with this drug for this condition at the time of application, **AND**
- Patient must have undergone ileal pouch anal anastomosis (IPAA) due to ulcerative colitis at least one year prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be confirmed based on the patient's symptoms, treatment history and baseline endoscopic examination of the pouch (pouchoscopy), **AND**
- Patient must have had a Modified Pouchitis Disease Activity Index (mPDAI) score of at least 5 at the time of initiating treatment with this drug for this condition, **AND**
- Patient must have had a minimum endoscopic mPDAI sub-score of at least 2 at the time of initiating treatment with this drug for this condition, **AND**
- Patient must have had at least 3 recurrent episodes of pouchitis within the year prior to initiating treatment with this drug for this condition, each of which was treated with at least 2 weeks of antibiotic or other prescription therapy; OR
- The condition must have required maintenance antibiotic therapy taken continuously for at least 4 weeks before commencing treatment with this drug, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must have been initiated in combination with standard of care antibiotic, **AND**
- Patient must have demonstrated a partial or complete response to treatment with this drug as determined by the treating clinician, for this condition if the patient has received non-PBS-subsidised treatment for the first three doses of induction.

#### **Treatment criteria:**

- Must be treated by a gastroenterologist (code 87); OR
- Must be treated by a consultant physician [internal medicine specialising in gastroenterology (code 81)]; OR
- Must be treated by a consultant physician [general medicine specialising in gastroenterology (code 82)].

The assessment of a patient's response to this course of treatment must be made after the third dose of vedolizumab so there is adequate time for a response to be demonstrated. The assessment must be made prior to obtaining a PBS authority for continuing treatment from the dose at week 14.

Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug.

The application for authorisation of treatment must be in writing and must include:

- (a) details of the proposed prescription; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes the following:
  - (i) the patient's baseline Modified Pouchitis Disease Activity Index (mPDAI) score and minimum endoscopic mPDAI sub-score; and
  - (ii) details of prior drug therapy for the condition [dosage, date of commencement and duration of therapy]; and
  - (iii) the date of commencement of this drug for this condition.

The endoscopic assessment contributing to the Modified Pouchitis Disease Activity Index score to confirm the patient's condition at baseline must have been performed no more than 4 weeks prior to initiation with non-PBS-subsidised treatment with this drug.

The prescriber must have excluded secondary causes of pouchitis, for example:

- (a) Ischaemia;
- (b) Crohn's disease (CD) or CD of the pouch;
- (c) Irritable pouch syndrome;
- (d) Predominant cuffitis;
- (e) Pouch stricture or pouch fistula;
- (f) Active infection;
- (g) NSAIDs;
- (h) Coeliac disease.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

### vedolizumab 300 mg injection, 1 vial

14670D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	2949.93	Entyvio [TK]

### *Mammalian target of rapamycin (mTOR) kinase inhibitors*

#### ■ EVEROLIMUS

**Caution** Careful monitoring of patients is mandatory.

##### Authority required (STREAMLINED)

**5795**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

##### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

##### Authority required (STREAMLINED)

**5554**

Management of cardiac allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

##### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of cardiac allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

### everolimus 250 microgram tablet, 60

5738B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*303.86	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

### everolimus 500 microgram tablet, 60

5739C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*530.42	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

### everolimus 750 microgram tablet, 60

5740D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*1591.24	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

### everolimus 1 mg tablet, 60

5737Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	4	5	..	*2121.68	<sup>a</sup> Certican [NV]	<sup>a</sup> Everocan [CR]

#### ■ SIROLIMUS

**Caution** Careful monitoring of patients is mandatory.

##### Authority required (STREAMLINED)

**5795**

Management of renal allograft rejection

Treatment Phase: Management (initiation, stabilisation and review of therapy)

##### **Clinical criteria:**

- Patient must be receiving this drug for prophylaxis of renal allograft rejection, **AND**
- The treatment must be under the supervision and direction of a transplant unit.

### sirolimus 1 mg/mL oral liquid, 60 mL

9550P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*924.02	Rapamune [PF]

### sirolimus 500 microgram tablet, 100

9747B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*587.54	Rapamune [PF]

### sirolimus 1 mg tablet, 100

9549N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1175.04	Rapamune [PF]

**sirolimus 2 mg tablet, 100**

9548M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*2350.12	Rapamune [PF]

**Complement inhibitors**

▪ **ECULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for four weeks of treatment, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- a) Presenting clinical features, including history, acute treatment and medications;
- b) Results of testing for genetic mutations (if available);
- c) Family history of aHUS, especially in first-degree relatives;
- d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than  $30 \times 10^9/L$  and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 4 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

Evidence of active and progressing TMA is defined by the following:

- (1) a platelet count of less than  $150 \times 10^9/L$ ; and evidence of two of the following:
  - (i) presence of schistocytes on blood film;
  - (ii) low or absent haptoglobin;

- (iii) lactate dehydrogenase (LDH) above normal range;
- OR
- (2) in recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; AND
- (3) evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:
  - (a) kidney impairment as demonstrated by one of the following:
    - (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment; and/or
    - (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment; or
    - (iii) a sCr of greater than the age-appropriate ULN in paediatric patients; or
    - (iv) a renal biopsy consistent with aHUS;
  - (b) onset of TMA-related neurological impairment;
  - (c) onset of TMA-related cardiac impairment;
  - (d) onset of TMA-related gastrointestinal impairment;
  - (e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised eculizumab (where possible), and should be supported by objective clinical measures. The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A detailed cover letter from the prescriber;
- (4) A measurement of body weight at the time of application;
- (5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;
- (6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result must be submitted to Services Australia within 27 days of commencement of eculizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised eculizumab treatment, under Initial treatment - Balance of Supply;
- (7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;
- (8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;
- (9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10191J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5358.60	Soliris [XI]

▪ **ECULIZUMAB**

- Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.
- Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab
- Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Balance of Supply' patient must qualify under the 'First Continuing Treatment' criteria.
- Note** This Balance of Supply restriction will cease to operate from 5 years after the date specified in the clinical criteria.
- Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001
- Note** No increase in the maximum number of repeats may be authorised.
- Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

HSD (Public)

Treatment Phase: Balance of Supply (transition from non-PBS-subsidised treatment during induction phase)

**Clinical criteria:**

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have received insufficient quantity to complete the induction treatment phase, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials to complete the induction treatment phase, as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10<sup>9</sup>/L)
- (iii) White Cell Count (x10<sup>9</sup>/L)
- (iv) Reticulocytes (x10<sup>9</sup>/L)
- (v) Neutrophils (x10<sup>9</sup>/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH)
- (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)

**eculizumab 300 mg/30 mL injection, 30 mL vial**

12900Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	5358.60	Soliris [XI]

▪ **ECULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Services Australia will contact the prescriber by telephone after a written application has been submitted.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 4 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)  
Treatment Phase: Initial treatment - Balance of Supply

**Clinical criteria:**

- Patient must have received PBS-subsidised initial supply of eculizumab for this condition, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion, and must have been submitted to Services Australia within 27 days of commencement of eculizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)  
Treatment Phase: Recommencement - Balance of Supply

**Clinical criteria:**

- Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition, **AND**
- Patient must not receive more than 20 weeks supply under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10190H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	5358.60	Soliris [XI]

▪ **ECULIZUMAB**

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia

Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - initial 1 (new patient) induction doses

**Clinical criteria:**

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10<sup>9</sup>/L)
- (iii) White Cell Count (x10<sup>9</sup>/L)
- (iv) Reticulocytes (x10<sup>9</sup>/L)
- (v) Neutrophils (x10<sup>9</sup>/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH)
- (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - (initial 3) switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)

**Clinical criteria:**

- Patient must be planning pregnancy; OR
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition, **AND**
- The treatment must not be in combination with any of (i) ravulizumab, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised pegcetacoplan - induction doses

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition, **AND**
- Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition, **AND**
- Patient must have developed resistance or intolerance to pegcetacoplan, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

12840T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	..	..	*42868.80	Soliris [XI]

▪ **ECULIZUMAB**

**Note** WARNING: Eculizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)

**Clinical criteria:**

- Patient must be planning pregnancy; OR
- Patient must be pregnant, **AND**
- Patient must have received PBS-subsidised treatment with ravulizumab for this condition, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Patient may qualify under this treatment phase more than once. In the event of miscarriage, patient may continue on eculizumab if patient is stable, and/or is planning a subsequent pregnancy. For continuing PBS-subsidised treatment, a 'Switching' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 1 (transition from non-PBS-subsidised treatment) - maintenance phase

**Clinical criteria:**

- Patient must have received non-PBS-subsidised eculizumab for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**



- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets (x10<sup>9</sup>/L)
- White Cell Count (x10<sup>9</sup>/L)
- Reticulocytes (x10<sup>9</sup>/L)
- Neutrophils (x10<sup>9</sup>/L)
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

**Note** This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather 2 (transition from LSDP-funded eculizumab)

**Clinical criteria:**

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with eculizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with eculizumab, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with eculizumab; OR

- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to commencing treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with eculizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets (x10<sup>9</sup>/L)
- White Cell Count (x10<sup>9</sup>/L)
- Reticulocytes (x10<sup>9</sup>/L)
- Neutrophils (x10<sup>9</sup>/L)
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition under an 'Initial', 'Balance of Supply', or 'Grandfather' treatment criteria, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets (x10<sup>9</sup>/L)
- White Cell Count (x10<sup>9</sup>/L)
- Reticulocytes (x10<sup>9</sup>/L)
- Neutrophils (x10<sup>9</sup>/L)
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place)

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Switch' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**eculizumab 300 mg/30 mL injection, 30 mL vial**

12877R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*32151.60	Soliris [XI]

▪ **ECULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

- Active malignancy;
- Active HIV infection;
- Hematopoietic stem cell transplants;
- Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised eculizumab under the initial treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the initial treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 80 weeks of eculizumab treatment in total under this restriction; OR
- Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and
- (2) One of the following:
  - a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
  - b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

- (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted;
- (5) A family history of aHUS, if applicable;
- (6) A history of kidney transplant if applicable (especially if required due to aHUS);
- (7) An inclusion of the individual consequences of recurrent disease, if applicable;
- (8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;
- (9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;
- (10) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI).

A maximum of up to 80 weeks of eculizumab treatment (or 104 weeks if switching C5 inhibitors during the course of initial and continuing treatment) is allowed under this restriction, however an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

## **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended Continuing treatment

### **Clinical criteria:**

- Patient must have received PBS-subsidised eculizumab under the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the extended continuing treatment phase for this condition, **AND**
- Patient must have demonstrated on-going treatment response with PBS-subsidised eculizumab for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and
- (2) One of the following:

- a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
- b) an eGFR within +/- 25% from baseline; or
- c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

- (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted;
- (5) A family history of aHUS, if applicable;
- (6) A history of multiple episodes of aHUS before commencing eculizumab treatment, if applicable;
- (7) A history of kidney transplant, if applicable (especially if required due to aHUS);
- (8) An inclusion of the individual consequences of recurrent disease;
- (9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment;
- (10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application;
- (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;
- (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

#### **Clinical criteria:**

- Patient must have demonstrated treatment response to previous treatment with PBS-subsidised eculizumab for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; **AND** (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count <150 x 10<sup>9</sup>/L); OR (iii) TMA-related organ impairment including on recent biopsy, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and
- (2) One of the following:
  - a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
  - b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline. PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

- (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted;
- (5) A family history of aHUS if applicable;
- (6) A history of multiple episodes of aHUS following the treatment break, if applicable;
- (7) A history of kidney transplant if applicable (especially if required due to aHUS);
- (8) An inclusion of the individual consequences of recurrent disease;
- (9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;
- (10) Evidence that the patient has had a treatment response to their previous treatment with eculizumab;
- (11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;
- (12) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** A raise in LDH alone is not a sufficient reason to recommence a C5 inhibitor, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider recommencement of C5 inhibitor treatment.

**Note** Kidney transplantation/dialysis is not a contraindication to recommencement of C5 inhibitor treatment.

## **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

### **Clinical criteria:**

- Patient must have received PBS-subsidised eculizumab under the recommencement of treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase for this condition; OR
- Patient must have received PBS-subsidised eculizumab under the switch from ravulizumab in the continuing recommencement of treatment phase for this condition, **AND**
- Patient must have demonstrated ongoing treatment response to 'Recommencement of treatment' with a C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with eculizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 24 weeks of treatment with eculizumab per continuing treatment course authorised under this restriction.

### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

- a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
- b) an eGFR within +/- 25% from baseline; or
- c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with eculizumab will not be permitted if a patient has experienced treatment failure with eculizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted;
- (5) A family history of aHUS, if applicable;
- (6) A history of multiple episodes of aHUS before recommencing eculizumab treatment, if applicable;
- (7) A history of kidney transplant if applicable (especially if required due to aHUS);
- (8) An inclusion of the individual consequences of recurrent disease, if applicable;
- (9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;
- (10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing eculizumab is severe extra-renal complications that have significantly improved;
- (11) If the indication for continuing eculizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with eculizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 4 weeks and up to 5 repeats, according to the specified dosage in the approved Product Information (PI). Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

#### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Switch from PBS-subsidised ravulizumab (all phases) - loading dose

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised ravulizumab under the 'Initial treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Extended continuing treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Continuing recommencement of treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised ravulizumab under the 'Grandfather (transitioning from non-PBS to PBS-subsidised treatment)' restriction for this condition, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 24 weeks of C5 inhibitor supply for this current treatment phase under this restriction.

#### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

The application must indicate the most recent treatment phase that the patient is switching from.

For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 24 weeks of treatment, according to the specified dosage in the approved Product Information (PI). An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength

requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**eculizumab 300 mg/30 mL injection, 30 mL vial**

10183Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	5358.60	Soliris [XI]

▪ **PEGCETACOPLAN**

**Caution** This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

**Note** Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab post pregnancy or from PBS-subsidised Complement 5 (C5) inhibitor for reasons other than post pregnancy

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 3 (switching from PBS-subsidised pegcetacoplan for pregnancy (induction doses)' criteria; OR
- Patient must have received prior PBS-subsidised treatment with at least one C5 inhibitor and returning to pegcetacoplan treatment for reasons other than post pregnancy, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

**Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets ( $\times 10^9/L$ )
- White Cell Count ( $\times 10^9/L$ )
- Reticulocytes ( $\times 10^9/L$ )
- Neutrophils ( $\times 10^9/L$ )
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place)

For the purposes of family planning, patient may qualify under this treatment phase more than once. To return to pegcetacoplan treatment for reasons other than post pregnancy, patient may qualify under this treatment phase once only in

HSD (Public)



any 12 consecutive months. Where long-term continuing PBS-subsidised treatment with pegcetacoplan is planned, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria of pegcetacoplan.

**pegcetacoplan 1.08 g/20 mL injection, 20 mL vial**

13175K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4343.86	Empaveli [ZO]

▪ **PEGCETACOPLAN**

**Caution** This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

**Note** Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)  
Treatment Phase: Initial treatment (new patient)

**Clinical criteria:**

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have PNH granulocyte clone size equal to or greater than 10% within the last 3 months, **AND**
- Patient must have experienced an inadequate response to a complement 5 (C5) inhibitor demonstrated by a haemoglobin level of less than 105 g/L; OR
- Patient must be intolerant to C5 inhibitors as determined by the treating physician, **AND**
- Patient must have received treatment with at least one C5 inhibitor for at least 3 months before initiating treatment with this drug unless intolerance of severity necessitating permanent treatment withdrawal had occurred, **AND**
- The treatment must be in combination with one PBS-subsidised C5 inhibitor for a period of 4 weeks during initiation of therapy.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

**Population criteria:**

- Patient must be at least 18 years of age.
- The authority application must be made in writing and must include:
- (1) a completed authority prescription form; and
  - (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
- At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information.
- At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:
- (i) Haemoglobin (g/L)
  - (ii) Platelets ( $\times 10^9/L$ )
  - (iii) White Cell Count ( $\times 10^9/L$ )
  - (iv) Reticulocytes ( $\times 10^9/L$ )
  - (v) Neutrophils ( $\times 10^9/L$ )
  - (vi) Granulocyte clone size (%)
  - (vii) Lactate Dehydrogenase (LDH)
  - (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
  - (ix) the LDH:ULN ratio (in figures, rounded to one decimal place)

**pegcetacoplan 1.08 g/20 mL injection, 20 mL vial**

13180Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	4343.86	Empaveli [ZO]

## ▪ PEGCETACOPLAN

**Caution** This drug increases the risk of encapsulated bacterial infections.

Consult the approved Product Information for information about vaccination against meningococcal, pneumococcal and Haemophilus influenzae type B (Hib) infection.

**Note** Prior to prescribing this drug, the prescriber must contact the pharmaceutical company to confirm that the patient has received all relevant vaccinations. The prescriber will then be provided with a Controlled Distribution Reference Number (CDRN) and information about the pumps and consumables for use.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First continuing treatment

### **Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction, **AND**
- The treatment must not be in combination with a Complement 5 (C5) inhibitor.

### **Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets ( $\times 10^9/L$ )
- White Cell Count ( $\times 10^9/L$ )
- Reticulocytes ( $\times 10^9/L$ )
- Neutrophils ( $\times 10^9/L$ )
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place)

### **Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must not be in combination with a Complement 5 (C5) inhibitor.

### **Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

### **Population criteria:**

- Patient must be at least 18 years of age.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners must request the appropriate number of vials for 4 weeks supply per dispensing as per the Product Information. A maximum of 5 repeats may be requested.

**pegcetacoplan 1.08 g/20 mL injection, 20 mL vial**

13185Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	4343.86	Empaveli [ZO]

▪ **RAVULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** See the following article/website for details on Expanded Disability Status Scale (EDSS): <https://www.ncbi.nlm.nih.gov/books/NBK222389/>.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Initial treatment - loading dose

**Clinical criteria:**

- Patient must have a confirmed diagnosis of NMOSD with aquaporin-4 immunoglobulin G auto-antibody (AQP4-IgG), **AND**
- Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must have had at least one relapse in the last 12 months, **AND**
- Patient must have experienced the most recent relapse while receiving treatment with rituximab; OR
- Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; OR
- Patient must have a documented contraindication to rituximab therapy, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for a single loading dose for induction therapy, according to the specified dosage in the approved Product Information (PI). Refer to the approved PI for patient weight ranges for the 100 mg/mL doses (consisting of 300 mg in 3 mL and 1.1 g in 11 mL vials).

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

The authority application must be in writing and must include all of the following:

- (1) details of the proposed authority prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the patient's Expanded Disability Status Scale (EDSS) score; and
  - (ii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy), or details of contraindications or developed intolerances necessitating treatment withdrawal.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**ravulizumab 1.1 g/11 mL injection, 11 mL vial**

14783C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	24105.11	Ultomiris [XI]

**ravulizumab 300 mg/3 mL injection, 3 mL vial**

14759T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6574.12	Ultomiris [XI]

## ▪ RAVULIZUMAB

**Note** WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 1 (new patient) induction dose

### **Clinical criteria:**

- Patient must not have received prior treatment with this drug for this condition, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10%, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

### **Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- (i) Haemoglobin (g/L)
- (ii) Platelets (x10<sup>9</sup>/L)
- (iii) White Cell Count (x10<sup>9</sup>/L)
- (iv) Reticulocytes (x10<sup>9</sup>/L)
- (v) Neutrophils (x10<sup>9</sup>/L)
- (vi) Granulocyte clone size (%)
- (vii) Lactate Dehydrogenase (LDH)
- (viii) the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- (ix) the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

### **Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Initial treatment - Initial 2 (switch from LSDP eculizumab) induction dose

### **Clinical criteria:**

- Patient must have previously received eculizumab for the treatment of this condition funded under the Australian Government's Life Saving Drugs Program (LSDP), **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to LSDP-funded treatment with eculizumab, **AND**

- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to LSDP-funded treatment with eculizumab, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to LSDP-funded treatment with eculizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to LSDP-funded treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to LSDP-funded treatment with eculizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab; OR
- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to LSDP-funded treatment with eculizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets (x10<sup>9</sup>/L)
- White Cell Count (x10<sup>9</sup>/L)
- Reticulocytes (x10<sup>9</sup>/L)
- Neutrophils (x10<sup>9</sup>/L)
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised eculizumab - induction dose

**Clinical criteria:**

- Patient must have received prior PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have received prior PBS-subsidised treatment with eculizumab through the 'Initial treatment - Initial 2 (switching from PBS-subsidised ravulizumab for pregnancy)' criteria, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a single loading dose based on the patient's weight, as per the Product Information

Patient may qualify under this treatment phase more than once for the purposes of family planning. Where long-term continuing PBS-subsidised treatment with this drug is planned, a 'Returning' patient may proceed under the 'Subsequent Continuing Treatment' criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Return from PBS-subsidised pegcetacoplan - induction doses

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with at least one Complement 5 (C5) inhibitor for this condition, **AND**
- Patient must have received PBS-subsidised treatment with pegcetacoplan for this condition, **AND**
- Patient must have developed resistance or intolerance to pegcetacoplan, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

For continuing PBS-subsidised treatment with this drug, a 'Returning' patient must proceed under the 'Subsequent Continuing Treatment' criteria.

**ravulizumab 1.1 g/11 mL injection, 11 mL vial**

12856P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	24105.11	Ultomiris [XI]

**ravulizumab 300 mg/3 mL injection, 3 mL vial**

12898W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6574.12	Ultomiris [XI]

▪ **RAVULIZUMAB**

**Note** WARNING: Ravulizumab increases the risk of meningococcal infections (septicaemia and/or meningitis). Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Grandfather (transition from non-PBS-subsidised treatment)

**Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 March 2022, **AND**
- Patient must have a diagnosis of PNH established by flow cytometry prior to commencing treatment with ravulizumab, **AND**
- Patient must have a PNH granulocyte clone size equal to or greater than 10% prior to commencing treatment with ravulizumab, **AND**
- Patient must have a raised lactate dehydrogenase value at least 1.5 times the upper limit of normal prior to commencing treatment with ravulizumab, **AND**
- Patient must have demonstrated clinical improvement or stabilisation of condition, the details of which must be kept with the patient's record, **AND**
- Patient must have experienced a thrombotic/embolic event which required anticoagulant therapy prior to commencing treatment with ravulizumab; OR
- Patient must have been transfused with at least 4 units of red blood cells in the last 12 months prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 70 g/L in the absence of anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have chronic/recurrent anaemia, where causes other than haemolysis have been excluded, together with multiple haemoglobin measurements not exceeding 100 g/L in addition to having anaemia symptoms prior to commencing treatment with ravulizumab; OR
- Patient must have debilitating shortness of breath/chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR
- Patient must have a history of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m<sup>2</sup>, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab; OR

- Patient must have recurrent episodes of severe pain requiring hospitalisation and/or narcotic analgesia, where causes other than PNH have been excluded prior to commencing treatment with ravulizumab, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets ( $\times 10^9/L$ )
- White Cell Count ( $\times 10^9/L$ )
- Reticulocytes ( $\times 10^9/L$ )
- Neutrophils ( $\times 10^9/L$ )
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place) must be at least 1.5

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'First Continuing Treatment' criteria.

**Note** This grandfather restriction will cease to operate from 5 years after the date specified in the clinical criteria.

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: First Continuing Treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug for this condition under the 'Initial' or 'Grandfather' treatment restriction, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

At the time of the authority application, details (result and date of result) of the following monitoring requirements must be provided:

- Haemoglobin (g/L)
- Platelets ( $\times 10^9/L$ )
- White Cell Count ( $\times 10^9/L$ )
- Reticulocytes ( $\times 10^9/L$ )
- Neutrophils ( $\times 10^9/L$ )
- Granulocyte clone size (%)
- Lactate Dehydrogenase (LDH)
- the upper limit of normal (ULN) for LDH as quoted by the reporting laboratory
- the LDH:ULN ratio (in figures, rounded to one decimal place)

**Authority required**

Paroxysmal nocturnal haemoglobinuria (PNH)

Treatment Phase: Subsequent Continuing Treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition under the 'First Continuing Treatment' or 'Return' criteria, **AND**
- Patient must have experienced clinical improvement as a result of treatment with this drug; OR
- Patient must have experienced a stabilisation of the condition as a result of treatment with this drug, **AND**
- The treatment must not be in combination with any of (i) another Complement 5 (C5) inhibitor, (ii) pegcetacoplan.

**Treatment criteria:**

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- Must be treated by a haematologist; OR
- Must be treated by a non-specialist medical physician who has consulted a haematologist on the patient's drug treatment details.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

At the time of the authority application, medical practitioners should request the appropriate number of vials for a maintenance dose based on the patient's weight, as per the Product Information. A maximum of 2 repeats may be requested.

### ravulizumab 1.1 g/11 mL injection, 11 mL vial

12883C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	24105.11	Ultomiris [XI]

### ravulizumab 300 mg/3 mL injection, 3 mL vial

12884D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6574.12	Ultomiris [XI]

## ■ RAVULIZUMAB

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** See the following article/website for details on Expanded Disability Status Scale (EDSS): <https://www.ncbi.nlm.nih.gov/books/NBK222389/>.

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

**Note** Special Pricing Arrangements apply.

### Authority required

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have an Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must not have experienced a relapse while receiving treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.

### **Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### Authority required

Neuromyelitis optica spectrum disorder (NMOSD)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

### **Clinical criteria:**

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 April 2025, **AND**
- Patient must have a confirmed diagnosis of NMOSD with AQP4-IgG prior to commencing treatment with this drug, **AND**
- Patient must have a recorded baseline Expanded Disability Status Scale (EDSS) score of no higher than 7 prior to commencing treatment with this drug, **AND**
- Patient must have had at least one relapse in the 12 months prior to commencing treatment with this drug for this condition, **AND**
- Patient must have received treatment with rituximab immediately prior to the most recent relapse prior to initiation of ravulizumab; OR
- Patient must have a documented intolerance to rituximab of a severity necessitating permanent treatment withdrawal; OR
- Patient must have a documented contraindication to rituximab therapy, **AND**
- Patient must have a current Expanded Disability Status Scale (EDSS) score of no higher than 7, **AND**
- Patient must not have experienced a relapse while receiving treatment with this drug for this condition, **AND**



- Patient must not receive more than 24 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a medical practitioner who has consulted a neurologist, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

The authority application must be in writing and must include all of the following:

- (1) details of the proposed authority prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice) which includes:
  - (i) the patient's baseline Expanded Disability Status Scale (EDSS) score before commencement with this drug for this condition; and
  - (ii) the patient's current Expanded Disability Status Scale (EDSS) score; and
  - (iii) details of prior rituximab treatment (dosage, date of commencement and duration of therapy), or details of contraindications or developed intolerances necessitating treatment withdrawal.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**ravulizumab 1.1 g/11 mL injection, 11 mL vial**

14758R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	24105.11	Ultomiris [XI]

**ravulizumab 300 mg/3 mL injection, 3 mL vial**

14784D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6574.12	Ultomiris [XI]

▪ **RAVULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

- a) Active malignancy;
- b) Active HIV infection;
- c) Hematopoietic stem cell transplants;
- d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;
- e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;
- f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 2 weeks of treatment, according to the specified dosage in the approved Product Information (PI). An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

## **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Initial treatment - Initial (new patient) loading dose

### **Clinical criteria:**

- Patient must have active and progressing thrombotic microangiopathy (TMA) caused by aHUS, **AND**
- Patient must have ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion; or, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion, patient must have platelet counts of greater than  $30 \times 10^9/L$  and a serum creatinine of greater than 150 mol/L, **AND**
- Patient must have a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days, **AND**
- Patient must have clinical features of active organ damage or impairment, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Evidence of active and progressing TMA is defined by the following:

(1) A platelet count of less than  $150 \times 10^9/L$ ; and evidence of at least two of the following:

- (i) presence of schistocytes on blood film;
- (ii) low or absent haptoglobin;
- (iii) lactate dehydrogenase (LDH) above normal range; or

(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and

(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one or more of the following:

- (i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment;
- (ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment;
- (iii) a sCr of greater than the age-appropriate ULN in paediatric patients;
- (iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.

The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A detailed cover letter from the prescriber;
- (4) A measurement of body weight at the time of application;
- (5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay;
- (6) In the case that a sample for ADAMTS-13 assay was not collected prior to plasma exchange or infusion, measurement of ADAMTS-13 activity must be taken 7-10 days following the last plasma exchange or infusion. The ADAMTS-13 result

must be submitted to Services Australia within 13 days of commencement of ravulizumab treatment in order for the patient to be considered as eligible for further PBS-subsidised C5 inhibitor treatment, under Initial balance of supply;

(7) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days;

(8) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of application;

(9) For all patients, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

Two authority prescription forms will be required to cover for the 26 weeks of initial therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

- a) Presenting clinical features, including history, acute treatment and medications;
- b) Results of testing for genetic mutations (if available);
- c) Family history of aHUS, especially in first-degree relatives;
- d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;
- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Switch from PBS-subsidised eculizumab (all phases) - loading dose

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised eculizumab under the 'Initial treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised eculizumab under the 'Continuing treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised eculizumab under the 'Extended continuing treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised eculizumab under the 'Recommencement of treatment' restriction for this condition; OR
- Patient must have previously received PBS-subsidised eculizumab under the 'Continuing recommencement of treatment' restriction for this condition, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must not receive more than 2 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**

• Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

The application must indicate the most recent treatment phase that the patient is switching from.

For patients who are switching C5 inhibitors, the next application should be sought under the next relevant treatment phase.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted.

### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Recommencement of treatment

#### **Clinical criteria:**

- Patient must have demonstrated treatment response to previous treatment with a PBS-subsidised C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must have the following clinical conditions prior to recommencing C5 inhibitor treatment: (i) either significant haemolysis as measured by low/absent haptoglobin; or presence of schistocytes on the blood film; or lactate dehydrogenase (LDH) above normal; **AND** (ii) either platelet consumption as measured by either 25% decline from patient baseline or thrombocytopenia (platelet count  $<150 \times 10^9/L$ ); OR (iii) TMA-related organ impairment including on recent biopsy.

#### **Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR

- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
  - Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.
- This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS if applicable;

(6) A history of multiple episodes of aHUS following the treatment break, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of TMA-related organ damage including current (within one week of application) haematological results (platelet count, haptoglobin and LDH), eGFR level, and, if applicable, on recent biopsy;

(10) Evidence that the patient has had a treatment response to their previous treatment with a C5 inhibitor;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

Two authority prescription forms will be required to cover for the 26 weeks of commencement therapy with ravulizumab, one for the loading dose and one for the 24 week balance which can be sought under the Balance of Supply.

**Note** A raise in LDH alone is not a sufficient reason to recommence a C5 inhibitor, but thrombocytopenia with one marker of haemolysis (such as raised LDH, presence of schistocytes, or low/absence of haptoglobin) is an accepted reason to consider commencement of C5 inhibitor treatment.

**Note** Kidney transplantation/dialysis is not a contraindication to commencement of C5 inhibitor treatment.

**ravulizumab 1.1 g/11 mL injection, 11 mL vial**

13809T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	24105.11	Ultomiris [XI]

**ravulizumab 300 mg/3 mL injection, 3 mL vial**

13808R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	6574.12	Ultomiris [XI]

▪ **RAVULIZUMAB**

**Caution** C5 inhibitors increase the risk of meningococcal infections (septicaemia and/or meningitis).

Please consult the approved PI for information about vaccination against meningococcal infection.

**Note** Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab

**Note** C5 inhibitors are not PBS-subsidised to treat TMA caused by conditions other than aHUS. Examples of TMA caused by conditions other than aHUS may include the following but not limited to:

a) Active malignancy;

b) Active HIV infection;

c) Hematopoietic stem cell transplants;

d) Various drugs including quinine, high-dose calcineurin inhibitors, antiplatelet agents;

e) Certain chemotherapy drugs or immunosuppressant drugs associated with microangiopathic haemolytic anaemia/TMA;

f) Active autoimmune diseases.

In cases where alternative causes of TMA have not been adequately excluded, additional information may be required from the prescriber to clarify the diagnosis before approval of the application.

**Note** Patients must be screened for genetic mutations known to confer a high risk of aHUS. These results should be submitted to Services Australia when they become available. Once the results have been submitted to Services Australia, they do not have to be resubmitted in subsequent applications.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Balance of Supply - maintenance doses

**Clinical criteria:**

- Patient must have received PBS-subsidised loading dose of ravulizumab for this condition for this current treatment phase, **AND**
- Patient must have/had ADAMTS-13 activity of greater than or equal to 10% on a blood sample, **AND**
- Patient must have received insufficient therapy to complete the maximum allowable treatment under their specified treatment phase, **AND**
- The treatment must provide no more than the balance of up to 24 weeks treatment available under the relevant treatment phase.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

ADAMTS-13 activity result must have been submitted to Services Australia. In the case that a sample for ADAMTS-13 activity taken prior to plasma exchange or infusion was not available at the time of application for Initial treatment, ADAMTS-13 activity must have been measured 7-10 days following the last plasma exchange or infusion and must have been submitted to Services Australia within 13 days of commencement of ravulizumab. The date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of the last, if any, plasma exchange or infusion that was undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay must also have been provided to Services Australia. Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment. An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** Services Australia will contact the prescriber by telephone after a written application has been submitted.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised ravulizumab under the initial treatment phase for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the grandfather restriction for this condition, **AND**
- Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 72 weeks of ravulizumab treatment in total under this restriction; OR
- Patient must not receive more than 104 weeks supply of a C5 inhibitor under the initial and continuing treatment restrictions if they had switched C5 inhibitors during the course of initial and continuing treatment, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**

- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time. This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

- (1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and
- (2) One of the following:
  - a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or
  - b) an eGFR within +/- 25% from baseline; or
  - c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

- (1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or
- (2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

- (1) A completed authority prescription form(s);
- (2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);
- (3) A measurement of body weight at the time of application;
- (4) Results of genetic testing, if not previously submitted;
- (5) A family history of aHUS, if applicable;
- (6) A history of kidney transplant if applicable (especially if required due to aHUS);
- (7) An inclusion of the individual consequences of recurrent disease, if applicable;
- (8) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;
- (9) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;
- (10) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

### **Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Extended continuing treatment

### **Clinical criteria:**

- Patient must have received PBS-subsidised ravulizumab under the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the continuing treatment phase for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab in the extended continuing treatment phase for this condition, **AND**
- Patient must have demonstrated ongoing treatment response with PBS-subsidised ravulizumab for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must have a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement; OR
- Patient must have severe TMA-related neurological impairment; OR
- Patient must have severe TMA-related gastrointestinal impairment; OR
- Patient must have severe TMA-related pulmonary impairment on current objective measurement; OR
- Patient must have grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min); OR
- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with ravulizumab, **AND**

- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before commencing ravulizumab treatment, if applicable;

(7) A history of kidney transplant, if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease;

(9) A supporting statement with clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment;

(10) Evidence that the patient has had a treatment response including haematological results of no more than 4 weeks old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 4 weeks old at the time of application;

(11) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(12) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Continuing recommencement of treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised ravulizumab under the 'Recommencement of treatment' restriction for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Recommencement treatment' restriction for this condition; OR
- Patient must have received PBS-subsidised ravulizumab under the switch from eculizumab 'Continuing recommencement treatment' restriction for this condition, **AND**

- Patient must have demonstrated ongoing treatment response to 'Recommendation of treatment' with a C5 inhibitor for this condition, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition in the most recent treatment phase, **AND**
- Patient must not receive more than 24 weeks of treatment with ravulizumab per continuing treatment course authorised under this restriction.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

A treatment response is defined as:

(1) Normalisation of haematology as demonstrated by at least 2 of the following: (i) platelet count, (ii) haptoglobin, (iii) lactate dehydrogenase (LDH); and

(2) One of the following:

a) an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor; or

b) an eGFR within +/- 25% from baseline; or

c) an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR 25% from baseline.

PBS-subsidised treatment with ravulizumab will not be permitted if a patient has experienced treatment failure with ravulizumab in the most recent treatment phase prior to the treatment phase where this application is sought.

A treatment failure is defined as a patient who is:

(1) Dialysis-dependent at the time of application and has failed to demonstrate significant resolution of extra-renal complications if originally presented; or

(2) On dialysis and has been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor, and has failed to demonstrate significant resolution of extra-renal complications if originally presented.

The authority application must include the following measures of response to the prior course of treatment, including serial haematological results (every 3 months while the patient is receiving treatment).

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A measurement of body weight at the time of application;

(4) Results of genetic testing, if not previously submitted;

(5) A family history of aHUS, if applicable;

(6) A history of multiple episodes of aHUS before recommencing ravulizumab treatment, if applicable;

(7) A history of kidney transplant if applicable (especially if required due to aHUS);

(8) An inclusion of the individual consequences of recurrent disease, if applicable;

(9) Evidence that the patient has had a treatment response including haematological results of no more than 1 week old at the time of application (platelet count, haptoglobin and LDH); and an eGFR level of no more than 1 week old at the time of application;

(10) Evidence that the patient has not experienced treatment failure, including a supporting statement with clinical evidence that the patient does not require dialysis, unless the indication for continuing ravulizumab is severe extra-renal complications that have significantly improved;

(11) If the indication for continuing ravulizumab is severe extra-renal complications, then a supporting statement with clinical evidence that any initial extra-renal complications of TMA have significantly improved is required.

This assessment must be submitted no later than 4 weeks from the cessation of the prior treatment. Where a response assessment is not undertaken and submitted within these timeframes, the patient will be deemed to have failed to respond to treatment with ravulizumab.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for 8 weeks of treatment and up to 2 repeats, according to the specified dosage in the approved Product Information (PI). With 2 repeat prescriptions, this treatment phase listing intends to provide approximately 24 weeks of treatment per continuing course, i.e., an authority application must be submitted every 24 weeks under this restriction if patient is deemed eligible.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Authority required**

Atypical haemolytic uraemic syndrome (aHUS)

Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements

**Clinical criteria:**

- Patient must have previously received non-PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS supply was commenced, the patient: (i) had active and progressing thrombotic microangiopathy (TMA) caused by aHUS; (ii) had ADAMTS-13 activity of greater than or equal to 10% on a blood sample



not confounded by any plasma exchange or infusion; (iii) had a confirmed negative STEC (Shiga toxin-producing E.Coli) result if the patient has had diarrhoea in the preceding 14 days of commencing ravulizumab treatment; (iv) had clinical features of active organ damage or impairment, **AND**

- Patient must have demonstrated ongoing treatment response with ravulizumab for this condition if received at least 26 weeks of initial non-PBS-subsidised therapy, **AND**
- Patient must not have experienced treatment failure with ravulizumab for this condition if they have received at least 26 weeks of initial non-PBS-subsidised therapy.

**Treatment criteria:**

- Must be treated by a prescriber who is either: (i) a haematologist, (ii) a nephrologist; OR
- Must be treated by a medical practitioner who has consulted at least one of the above mentioned specialist types, with agreement reached that the patient should be treated with this pharmaceutical benefit on this occasion, **AND**
- Patient must be undergoing treatment with one C5 inhibitor therapy only at any given time.

This drug is not PBS-subsidised if it is prescribed to an in-patient in a public hospital setting.

Evidence of active and progressing TMA is defined by the following:

(1) A platelet count of less than  $150 \times 10^9/L$ ; and evidence of at least two of the following:

(i) presence of schistocytes on blood film;

(ii) low or absent haptoglobin;

(iii) lactate dehydrogenase (LDH) above normal range; or

(2) In recipients of a kidney transplant for end-stage kidney disease due to aHUS, a kidney biopsy confirming TMA; and

(3) Evidence of at least one of the following clinical features of active TMA-related organ damage or impairment is defined as below:

(a) kidney impairment as demonstrated by one or more of the following:

(i) a decline in estimated Glomerular Filtration Rate (eGFR) of greater than 20% in a patient who has pre-existing kidney impairment;

(ii) a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment;

(iii) a sCr of greater than the age-appropriate ULN in paediatric patients;

(iv) a renal biopsy consistent with aHUS;

(b) onset of TMA-related neurological impairment;

(c) onset of TMA-related cardiac impairment;

(d) onset of TMA-related gastrointestinal impairment;

(e) onset of TMA-related pulmonary impairment.

Claims of non-renal TMA-related organ damage should be made at the point of application for initial PBS-subsidised ravulizumab (where possible), and should be supported by objective clinical measures.

The prescriber's cover letter should establish that the observed organ damage is directly linked to active and progressing TMA, particularly when indirect causes such as severe thrombocytopenia, hypertension and acute renal failure are present at the time of the initial organ impairment.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

The authority application must be in writing and must include all of the following:

(1) A completed authority prescription form(s);

(2) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice);

(3) A detailed cover letter from the prescriber;

(4) A measurement of body weight at the time of application;

(5) The result of ADAMTS-13 activity on a blood sample taken prior to plasma exchange or infusion; the date and time that the sample for the ADAMTS-13 assay was collected, and the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to collection of the ADAMTS-13 assay;

(6) A confirmed negative STEC result if the patient has had diarrhoea in the preceding 14 days of initiating treatment with non-PBS-subsidised ravulizumab;

(7) Evidence of active and progressing TMA, including pathology results where relevant. Evidence of the onset of TMA-related neurological, cardiac, gastrointestinal or pulmonary impairment requires a supporting statement with clinical evidence in patient records. All tests must have been performed within 4 weeks of commencement of non-PBS-subsidised ravulizumab;

(8) For patients who have received at least 26 weeks of ravulizumab treatment, a recent measurement of eGFR, platelets and two of either LDH, haptoglobin or schistocytes of no more than 1 week old at the time of application.

**Note** At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug for the balance of the current treatment phase. 8 weeks of treatment and up to 2 repeats according to the specified dosage in the approved Product Information (PI) may be sought.

An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Consider strengths and combinations that minimise drug wastage. A separate authority prescription form must be completed for each strength requested.

Applications for treatment with this drug where the dose and dosing frequency exceeds that specified in the approved PI will not be approved.

**Note** The Authority application should be accompanied by a cover letter from the prescriber, providing complete details on:

a) Presenting clinical features, including history, acute treatment and medications;

b) Results of testing for genetic mutations (if available);

c) Family history of aHUS, especially in first-degree relatives;

d) Patient's prior history of episodes of active and progressing TMA caused by aHUS;

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

- e) Exclusion of alternative causes of TMA;
- f) History of renal or other organ transplant (if any);
- g) Any other matters considered relevant by the prescriber.

In cases where there are discordant results (for example, an equivocal biopsy result in the absence of objective evidence of haemolysis) the cover letter should articulate the prescriber's interpretation of the clinical data and how a diagnosis of aHUS is supported by the available evidence.

**Note** Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

### ravulizumab 1.1 g/11 mL injection, 11 mL vial

13797E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	24105.11	Ultomiris [XI]

### ravulizumab 300 mg/3 mL injection, 3 mL vial

13785M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	6574.12	Ultomiris [XI]

### Other immunosuppressants

#### ▪ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatrix - Viatrix Care.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### Authority required

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle

#### **Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple

myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**lenalidomide 10 mg capsule, 21**

12061T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	822.66	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 15 mg capsule, 21**

12026Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	990.80	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 25 mg capsule, 21**

12059Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1296.30	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 5 mg capsule, 21**

12034J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	627.96	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 20 mg capsule, 21**

14592B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	1266.69	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 2 cycles under this restriction.

**lenalidomide 10 mg capsule, 21**

12057N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	822.66	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 15 mg capsule, 21**

12062W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	990.80	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 25 mg capsule, 21**

12036L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1296.30	Lenalide [JU]	Lenalidomide Dr.Reddy's [RI]

# ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Lenalidomide Sandoz [SZ]  
Revlimid [BQ]

Lenalidomide Viatris [AF]

## lenalidomide 5 mg capsule, 21

12039P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	627.96	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 20 mg capsule, 21

14633E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	1	..	1266.69	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

## ■ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### **Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone

### **Treatment criteria:**

- Patient must be undergoing concurrent treatment with elotuzumab obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

## lenalidomide 10 mg capsule, 21

12988N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	822.66	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 15 mg capsule, 21

12991R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	990.80	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 25 mg capsule, 21

12979D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1296.30	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 5 mg capsule, 21

12985K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	627.96	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

## lenalidomide 20 mg capsule, 21

14616G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1266.69	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

## ■ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

### **Authority required**

Relapsed and/or refractory multiple myeloma

Treatment Phase: Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone

**Treatment criteria:**

- Patient must be undergoing concurrent treatment with carfilzomib obtained through the PBS, **AND**
- Patient must not be undergoing simultaneous treatment with this drug obtained under another PBS listing.

**lenalidomide 10 mg capsule, 21**

13661B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	822.66	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 15 mg capsule, 21**

13641Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	990.80	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 25 mg capsule, 21**

13630J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1296.30	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 5 mg capsule, 21**

13636Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	627.96	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 20 mg capsule, 21**

14608W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1266.69	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- The treatment must be limited to a maximum duration of 16 weeks, **AND**
- Patient must be classified as Low risk or Intermediate-1 according to the International Prognostic Scoring System (IPSS), **AND**
- Patient must have a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, **AND**
- Patient must be red blood cell transfusion dependent.

Classification of a patient as Low risk requires a score of 0 on the IPSS, achieved with the following combination: less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias.

Classification of a patient as Intermediate-1 requires a score of 0.5 to 1 on the IPSS, achieved with the following possible combinations:

1. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 0/1 cytopenias; OR
2. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR
3. less than 5% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR
4. less than 5% marrow blasts with intermediate karyotypic status (other abnormalities), and 2/3 cytopenias; OR
5. 5%-10% marrow blasts with intermediate karyotypic status (other abnormalities), and 0/1 cytopenias; OR

6. 5%-10% marrow blasts with good karyotypic status (normal, -Y alone, -5q alone, -20q alone), and 2/3 cytopenias; OR  
 7. less than 5% marrow blasts with poor karyotypic status (complex, greater than 3 abnormalities), and 0/1 cytopenias.  
 Classification of a patient as red blood cell transfusion dependent requires that:

- (i) the patient has been transfused within the last 8 weeks; and
- (ii) the patient has received at least 8 units of red blood cell in the last 6 months prior to commencing PBS-subsidised therapy with lenalidomide; and would be expected to continue this requirement without lenalidomide treatment.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (a) details (date, unique identifying number/code or provider number) of the bone marrow biopsy report from an Approved Pathology Authority demonstrating that the patient has myelodysplastic syndrome; and
- (b) details (date, unique identifying number/code or provider number) of the full blood examination report; and
- (c) details (date, unique identifying number/code or provider number) of the pathology report and details of the cytogenetics demonstrating Low risk or Intermediate-1 disease according to the IPSS (note: using Fluorescence in Situ Hybridization (FISH) to demonstrate MDS -5q is acceptable); and
- (d) details of transfusion requirements including: (i) the date of most recent transfusion and the number of red blood cell units transfused; and (ii) the total number of red blood cell units transfused in the 4 and 6 months preceding the date of this application.

All the reports must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Myelodysplastic syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have received PBS-subsidised initial therapy with lenalidomide for myelodysplastic syndrome, **AND**
- Patient must have achieved and maintained transfusion independence; or at least a 50% reduction in red blood cell unit transfusion requirements compared with the four month period prior to commencing initial PBS-subsidised therapy with lenalidomide, **AND**
- Patient must not have progressive disease, **AND**
- The condition must not have progressed to acute myeloid leukaemia.

The first authority application for continuing supply must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail. Subsequent authority applications for continuing supply may be made via the Online PBS Authorities System or by telephone.

The following evidence of response must be provided at each application:

- (i) a haemoglobin level taken within the last 4 weeks; and
- (ii) the date of the last transfusion; and
- (iii) a statement of the number of units of red cells transfused in the 4 months immediately preceding this application;

All reports must be documented in the patient's medical records.

For first continuing applications, if the application is submitted through HPOS form upload or mail, it must include:

- (a) a completed authority prescription form; and
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**lenalidomide 10 mg capsule, 21**

2802L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	822.66	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

**lenalidomide 5 mg capsule, 21**

2799H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	627.96	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatris [AF]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatris - Viatris Care.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
  - The condition must be confirmed by a histological diagnosis, **AND**
  - Patient must be ineligible for a primary stem cell transplantation, **AND**
  - The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.
- The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma, and
- (2) confirmation of ineligibility for prior stem cell transplant; and
- (3) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

## ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

### lenalidomide 10 mg capsule, 21

11064H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	822.66	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 15 mg capsule, 21

11062F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	990.80	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 25 mg capsule, 21

11041D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1296.30	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 5 mg capsule, 21

11029L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	627.96	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

### lenalidomide 20 mg capsule, 21

14632D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1266.69	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

## ▪ LENALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatrix - Viatrix Care.

### Authority required

Multiple myeloma

Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease

### **Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have undergone an autologous stem cell transplant (ASCT) as part of frontline therapy for newly diagnosed multiple myeloma, **AND**
- Patient must not have progressive disease following autologous stem cell transplant (ASCT).

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and
- (2) the date the autologous stem cell transplant was performed; and
- (3) nomination of which disease activity parameters will be used to assess progression.

To enable confirmation of eligibility for treatment, the details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f) of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine progression, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.



All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)) Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be as monotherapy.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**lenalidomide 5 mg capsule, 28**

11967W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	837.28	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 10 mg capsule, 28**

11968X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1096.88	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 15 mg capsule, 28**

11964Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1321.06	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatrix - Viatrix Care.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle

**Clinical criteria:**

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have been treated with lenalidomide or bortezomib for this condition, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

The authority application must be made via the online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and

(2) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or
- (g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held on the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)

**Clinical criteria:**

- Patient must have received PBS-subsidised treatment with this drug under the treatment phase covering cycles 1 to 4, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- The treatment must not exceed a total of 4 cycles under this restriction.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**lenalidomide 10 mg capsule, 14**

12070G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	548.44	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 15 mg capsule, 14**

12012F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	660.53	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 25 mg capsule, 14**

12019N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	864.20	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 5 mg capsule, 14**

12035K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	3	..	418.64	Lenalide [JU] Lenalidomide Sandoz [SZ]	Lenalidomide Dr.Reddy's [RI] Revlimid [BQ]

**lenalidomide 20 mg capsule, 14**

14623P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	844.46	Lenalide [JU]

▪ **LENALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. If lenalidomide is taken during pregnancy, a teratogenic effect of lenalidomide in humans cannot be ruled out.

**Note** Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed: Revlimid - i-access program; Lenalidomide Dr.Reddy's - Reddy-2-Assist Controlled Access Program; Lenalide - Juno Connected™; Lenalidomide Sandoz - MyCheckPoint Pregnancy Prevention Program; Lenalidomide Viatrix - Viatrix Care.

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; **OR**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein. The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the histological report confirming the diagnosis of multiple myeloma; and
- (2) prior treatments including name(s) of drug(s) and date of most recent treatment cycle; and
- (3) date of prior stem cell transplant or confirmation of ineligibility for prior stem cell transplant; and
- (4) details of the basis of the diagnosis of progressive disease or failure to respond; and
- (5) nomination of which disease activity parameters will be used to assess response.

To enable confirmation of eligibility for treatment, details (date, unique identifying number/code or provider number) of the current diagnostic reports (for items a, b, c, d, f (if applicable), g), or, confirmation that diagnosis was based on (for items e, f), of at least one of the following must be provided:

- (a) the level of serum monoclonal protein; or
- (b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or
- (c) the serum level of free kappa and lambda light chains; or
- (d) bone marrow aspirate or trephine - the percentage of plasma cells; or
- (e) if present, the size and location of lytic bone lesions (not including compression fractures); or
- (f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be stated/declared. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be held in the patient's medical records.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for relapsed or refractory multiple myeloma, **AND**
- The treatment must be as monotherapy; OR
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**lenalidomide 10 mg capsule, 21**

5784K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	822.66	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 15 mg capsule, 21**

5785L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	990.80	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 25 mg capsule, 21**

5786M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1296.30	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 5 mg capsule, 21**

5783J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	627.96	Lenalide [JU] Lenalidomide Sandoz [SZ] Revlimid [BQ]	Lenalidomide Dr.Reddy's [RI] Lenalidomide Viatrix [AF]

**lenalidomide 20 mg capsule, 21**

14588T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1266.69	<sup>a</sup> Lenalide [JU]	<sup>a</sup> Lenalidomide Sandoz [SZ]

**■ POMALIDOMIDE**

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalyst - i-access program; Pomalidomide Sandoz - Pregnancy Prevention Program.

HSD (Public)

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Multiple myeloma

Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone)

**Clinical criteria:**

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy that is either: (i) lenalidomide monotherapy, (ii) contains lenalidomide, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**Authority required**

Multiple myeloma

Treatment Phase: Continuing treatment with triple therapy (this drug, bortezomib and dexamethasone)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited to: (i) this drug, (ii) bortezomib, (iii) dexamethasone, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

**pomalidomide 3 mg capsule, 14**

12666P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	1662.92	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [BQ]

**pomalidomide 4 mg capsule, 14**

12665N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	2	..	2217.22	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [BQ]

**pomalidomide 1 mg capsule, 14**

13794B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	621.91	Pomolide [JU]

**pomalidomide 2 mg capsule, 14**

13815D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	1108.61	Pomolide [JU]

## ▪ POMALIDOMIDE

**Caution** This drug is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving pomalidomide under the PBS listing must be registered in the risk management program relevant for the brand of pomalidomide being prescribed and dispensed: Pomolide - Juno's Pregnancy Prevention Program; Pomalyst - i-access program; Pomalidomide Sandoz - Pregnancy Prevention Program.

### Authority required

Multiple myeloma

Treatment Phase: Initial treatment - dual therapy in combination with dexamethasone

### **Clinical criteria:**

- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must have experienced treatment failure with lenalidomide, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must have experienced treatment failure with bortezomib, unless contraindicated or not tolerated according to the Therapeutic Goods Administration (TGA) approved Product Information.

Bortezomib treatment failure is the absence of achieving at least a partial response or as progressive disease during treatment or within 6 months of discontinuing treatment with bortezomib. Lenalidomide treatment failure is progressive disease during treatment or within 6 months of discontinuing treatment with lenalidomide.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
- (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
- (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or
- (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
- (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
- (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
- (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

- (1) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with lenalidomide, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to lenalidomide according to the relevant TGA-approved Product Information; and
- (2) details (date, unique identifying number/code or provider number) of the reports demonstrating the patient has failed treatment with bortezomib, including the dates of treatment or the details of the contraindication to or details of the nature and severity of the intolerance to bortezomib according to the relevant TGA-approved Product Information.

All reports must be documented in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Multiple myeloma

Treatment Phase: Continuing treatment - dual therapy in combination with dexamethasone

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of dual combination therapy limited to: (i) this drug, (ii) dexamethasone.

Progressive disease is defined as at least 1 of the following:

- (a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or  
 (b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or  
 (c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or  
 (d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or  
 (e) an increase in the size or number of lytic bone lesions (not including compression fractures); or  
 (f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or  
 (g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### pomalidomide 4 mg capsule, 21

10387Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	3325.83	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [BQ]

#### pomalidomide 1 mg capsule, 21

13803L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	932.87	Pomalidomide Sandoz [SZ]	Pomolide [JU]

#### pomalidomide 3 mg capsule, 21

10406Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	2494.38	Pomalidomide Sandoz [SZ] Pomolide [JU]	Pomalyst [BQ]

#### pomalidomide 2 mg capsule, 21

13788Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	1662.92	Pomalidomide Sandoz [SZ]	Pomolide [JU]

### ■ THALIDOMIDE

**Caution** Thalidomide is a category X drug and must not be given to pregnant women. Pregnancy in female patients or in the partners of male patients must be avoided during treatment and for 1 month after cessation of treatment.

**Note** Patients receiving thalidomide under the PBS listing must be registered in the i-access risk management program.

#### Authority required (STREAMLINED)

**5914**

Multiple myeloma

#### thalidomide 100 mg capsule, 28

9667T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*1061.38	Thalomid [BQ]

#### thalidomide 50 mg capsule, 28

9566L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	..	..	*1061.40	Thalomid [BQ]

### ■ MUSCULO-SKELETAL SYSTEM

#### ■ MUSCLE RELAXANTS

##### MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS

##### *Other centrally acting agents*

### ■ BACLOFEN

#### Authority required (STREAMLINED)

**7152**

Severe chronic spasticity

#### Clinical criteria:

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

#### Authority required (STREAMLINED)

**7134**

Severe chronic spasticity

#### Clinical criteria:

# MUSCULO-SKELETAL SYSTEM

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required (STREAMLINED)**

**7153**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required (STREAMLINED)**

**7148**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

**baclofen 40 mg/20 mL intrathecal injection, 20 mL ampoule**

11195F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	..	..	*611.38	Sintetica Baclofen Intrathecal [BZ]

■ **BACLOFEN**

**Note** Pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule and pharmaceutical benefits that have the form baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**6925**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity of cerebral origin.

**Authority required (STREAMLINED)**

**6939**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to multiple sclerosis.

**Authority required (STREAMLINED)**

**6940**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord injury.

**Authority required (STREAMLINED)**

**6911**

Severe chronic spasticity

**Clinical criteria:**

- Patient must have failed to respond to treatment with oral antispastic agents; OR
- Patient must have had unacceptable side effects to treatment with oral antispastic agents, **AND**
- Patient must have chronic spasticity due to spinal cord disease.

**baclofen 10 mg/5 mL intrathecal injection, 10 x 5 mL ampoules**

11126N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	762.70	<sup>a</sup> Sintetica Baclofen Intrathecal [BZ]

**baclofen 10 mg/5 mL intrathecal injection, 5 mL ampoule**

5617P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*762.70	<sup>a</sup> Bacthecal [DZ]	<sup>a</sup> Lioresal Intrathecal [NV]

■ **DRUGS FOR TREATMENT OF BONE DISEASES**

**DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION**

*Bisphosphonates*

HSD (Public)



## ■ PAMIDRONATE DISODIUM

### Authority required (STREAMLINED)

**4433**

Hypercalcaemia of malignancy

#### Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

### pamidronate disodium 15 mg/5 mL injection, 5 mL vial

5667G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	2	..	*55.24	Pamisol [PF]

### pamidronate disodium 30 mg/10 mL injection, 10 mL vial

5668H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	2	..	*55.26	Pamisol [PF]

### pamidronate disodium 60 mg/10 mL injection, 10 mL vial

5669J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	55.26	Pamisol [PF]

## ■ PAMIDRONATE DISODIUM

### Authority required (STREAMLINED)

**4433**

Hypercalcaemia of malignancy

#### Clinical criteria:

- Patient must have a malignancy refractory to anti-neoplastic therapy.

### Authority required (STREAMLINED)

**5218**

Multiple myeloma

### Authority required (STREAMLINED)

**5291**

Bone metastases

#### Clinical criteria:

- The condition must be due to breast cancer.

### pamidronate disodium 90 mg/10 mL injection, 10 mL vial

5670K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	11	..	82.89	Pamisol [PF]

## ■ ZOLEDRONIC ACID

### Authority required (STREAMLINED)

**14735**

Adjuvant management of breast cancer

#### Population criteria:

- Patient must be post-menopausal.

#### Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment with this drug for this indication for more than 36 months.

### zoledronic acid 4 mg/5 mL injection, 5 mL vial

13773X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	59.56	<sup>a</sup> DEZTRON [DZ] <sup>a</sup> Zoledronic Acid Accord [OC]	<sup>a</sup> Zoledronate-DRLA 4 [RZ]

## ■ ZOLEDRONIC ACID

### Authority required (STREAMLINED)

**5735**

Multiple myeloma

### Authority required (STREAMLINED)

**5605**

Bone metastases

#### Clinical criteria:

- The condition must be due to breast cancer.

### Authority required (STREAMLINED)

**5703**

Bone metastases

#### Clinical criteria:

- The condition must be due to castration-resistant prostate cancer.

### Authority required (STREAMLINED)

**5704**

Hypercalcaemia of malignancy

**Clinical criteria:**

- Patient must have a malignancy refractory to anti-neoplastic therapy.

**zoledronic acid 4 mg/5 mL injection, 5 mL vial**

9653C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	11	..	59.56	<sup>a</sup> APO-Zoledronic Acid [TX] <sup>a</sup> Zoledronate-DRLA 4 [RZ] <sup>a</sup> Zometa [SA]	<sup>a</sup> DEZTRON [DZ] <sup>a</sup> Zoledronic Acid Accord [OC]

*Other drugs affecting bone structure and mineralization*

▪ **BUROSUMAB**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** Special Pricing Arrangements apply.

**Authority required**

X-linked hypophosphataemia

Treatment Phase: Initial treatment - New patient

**Clinical criteria:**

- Patient must have a documented confirmation of PHEX pathogenic variant; OR
- Patient must have a confirmed diagnosis of X-linked hypophosphataemia demonstrated by the presence of all of the following: (i) a serum phosphate concentration below the age adjusted lower limit of normal; (ii) current or historical (for those with growth plate fusion) radiographic X-ray evidence of rickets; (iii) elevated (or inappropriately normal) serum or plasma FGF-23 levels of above the mean of the assay-specific reference range; (iv) renal phosphate wasting demonstrated by a ratio of tubular maximum reabsorption rate of phosphate to glomerular filtration rate (TmP/GFR) according to age specific normal ranges using the second morning urine void and paired serum sample measuring phosphate and creatinine.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.
- At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

**Authority required**

X-linked hypophosphataemia

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved normalisation in serum phosphate levels, **AND**
- Patient must have radiographical evidence of stabilisation/improvement in rickets in patients without growth plate fusion.

**Treatment criteria:**

- Must be treated by a medical practitioner identifying as at least one of the following specialists: (i) paediatric endocrinologist, (ii) paediatric nephrologist, (iii) endocrinologist, (iv) nephrologist.
- Where adequate response to treatment with this drug cannot be demonstrated, the treating physician must confirm that continuing therapy has been determined to be clinically required by a second specialist physician with expertise in the treatment of X-linked hypophosphataemia.

At the time of authority application, medical practitioners must request the appropriate number of vials of appropriate strength(s) to provide sufficient drug, based on the weight of the patient, adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). A separate authority prescription form must be completed for each strength requested. Up to a maximum of 5 repeats will be authorised.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

**burosumab 30 mg/mL injection, 1 mL vial**

13155J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	11997.00	Crysvita [KO]

**burosumab 20 mg/mL injection, 1 mL vial**

13145W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	7998.00	Crysvita [KO]

**burosumab 10 mg/mL injection, 1 mL vial**

13140N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	3999.00	Crysvita [KO]

## OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

### OTHER DRUGS FOR DISORDERS OF THE MUSCULO-SKELETAL SYSTEM

#### *Other drugs for disorders of the musculo-skeletal system*

#### ■ NUSINERSEN

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA (1 or 2 copies of the SMN2 gene) listing

#### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

#### **Population criteria:**

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug. Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

#### **nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

11378W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	104500.00	Spinraza [BD]

#### ■ NUSINERSEN

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Note** Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. **Muscle & Nerve** 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. **PLoS ONE** 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. **American Journal of Respiratory and Critical Care Medicine** 166(1), pp 111-117

The National Health Foundation of Australia has 6MWT test standardised instructions and recording forms located at: <https://www.heartonline.org.au/resources/documents-and-links#exercise>

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. **Muscle & Nerve** 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. **Neurology** April (15 Supplement) P4.452

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

**Clinical criteria:**

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HF MSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

13068T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	104500.00	Spinraza [BD]

▪ **NUSINERSEN**

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

**Clinical criteria:**

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

13084P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	104500.00	Spinraza [BD]

## ■ NUSINERSEN

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

### Authority required

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of a patient commenced on this drug under the pre-symptomatic SMA (3 copies of the SMN2 gene) listing

### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or initiated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

### **Population criteria:**

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised risdiplam to PBS-subsidised nusinersen for this condition a wash out period may be required.

### **nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

14095W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	104500.00	Spinraza [BD]

## ■ NUSINERSEN

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

### Authority required

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment - Loading doses

### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must be untreated with gene therapy.

**Population criteria:**

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:

- i) Onset before 6 months of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- i) Onset between 6 and 18 months; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Weakness in trunk righting/derotation; or
- v) Hypotonia; or
- vi) Absence of deep tendon reflexes; or
- vii) Failure to gain weight appropriate for age; or
- viii) Any active chronic neurogenic changes; or
- ix) A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- i) Onset between 18 months and 3 years of age; and
- ii) Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- iii) Proximal weakness; or
- iv) Hypotonia; or
- v) Absence of deep tendon reflexes; or
- vi) Failure to gain weight appropriate for age; or
- vii) Any active chronic neurogenic changes; or
- viii) A compound muscle action potential below normative values for an age-matched child.

Application for authorisation of initial treatment must be in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
  - i) specification of SMA type (I, II or IIIa); and
  - ii) sign(s) and symptom(s) that the patient has experienced; and
  - iii) patient's age at the onset of sign(s) and symptom(s).

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

11363C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104500.00	Spinraza [BD]

▪ **NUSINERSEN**

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

#### **Authority required**

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 1 or 2 copies of the SMN2 gene - Loading doses

#### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

#### **Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must be untreated with gene therapy.

#### **Population criteria:**

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) a completed authority prescription form; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

#### **nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

12177X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104500.00	Spinraza [BD]

#### ▪ NUSINERSEN

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** For the next authority application after this application, continue treatment through the 'Treatment phase:

Continuing/maintenance treatment of either symptomatic Type I, II or IIIa SMA, or of a patient commenced on this drug under the pre-symptomatic SMA listing' under the indication: 'Spinal muscular atrophy (SMA)'.

#### **Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with one of: (i) Type 1 SMA, or, (ii) pre-symptomatic SMA

#### **Clinical criteria:**

- Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this: (i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples), **AND**

- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with risdiplam for this condition.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type.

**Population criteria:**

- Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy; OR
- Patient must have a prior authority approval for any drug PBS-listed for pre-symptomatic SMA, with at least one approval having been for gene therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for one of the following:

- (i) Symptomatic Type 1 SMA; or
- (ii) Pre-symptomatic SMA treated with nusinersen.

Definition:

Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.

0. Absence of developmental states (1 to 9) listed below:

1. Rolls from side to side on back;
2. Child holds head erect for at least 3 seconds unsupported;
3. Sitting, but with assistance;
4. Sitting without assistance:
  - (a) Child sits up straight with the head erect for at least 10 seconds;
  - (b) Child does not use arms or hands to balance body or support position.

5. Hands and knees crawling:

- (a) Child alternately moves forward or backwards on hands and knees;
- (b) The stomach does not touch the supporting surface;
- (c) There are continuous and consecutive movements at least 3 in a row.

6. Standing with assistance:

- (a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object;
- (b) The body does not touch the stable object, and the legs support most of the body weight;
- (c) Child thus stands with assistance for at least 10 seconds.

7. Standing alone:

- (a) Child stands in upright position on both feet (not on the toes) with the back straight;
- (b) The leg supports 100% of the child's weight;
- (c) There is no contact with a person or object;
- (d) Child stands alone for at least 10 seconds.

8. Walking with assistance:

- (a) Child is in an upright position with the back straight;
- (b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;
- (c) One leg moves forward while the other supports part of the body weight;
- (d) Child takes at least 5 steps in this manner.

9. Walking alone:

- (a) Child takes at least 5 steps independently in upright position with the back straight;
- (b) One leg moves forward while the other supports most of the body weight;
- (c) There is no contact with a person or object.

Confirm which developmental state has regressed by: (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i)).

Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

12972R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104500.00	Spinraza [BD]



## ■ NUSINERSEN

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

### **Authority required**

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene - Loading doses

### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA.

### **Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not exceed four loading doses (at days 0, 14, 28 and 63) under this restriction, **AND**
- Patient must be untreated with gene therapy.

### **Population criteria:**

- Patient must be aged under 36 months prior to commencing treatment.  
Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) a completed authority prescription form; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

### **nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

14099C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104500.00	Spinraza [BD]

## ■ NUSINERSEN

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

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

**Note** Special Pricing Arrangements apply.

### **Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in an adult who did not initiate PBS subsidy during childhood

### **Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

### **Population criteria:**

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood, **AND**
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19<sup>th</sup> birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Failure to gain weight appropriate for age,
- (vi) Any active denervation or chronic neurogenic changes found on electromyography,
- (vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,
- (2) which of the above (i to vii) (at least 1) were present during childhood,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Changing the prescribed therapy

**Treatment criteria:**

- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19<sup>th</sup> birthday, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- Patient must be untreated with gene therapy, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.

**Note** Subsequent changes in the prescribed drug where applicable are to occur under the 'Continuing treatment' phase listing of the drug that therapy is changing to.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

13052Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104500.00	Spinraza [BD]

**■ NUSINERSEN**

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment in a child

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

**Population criteria:**

- Patient must be of an age that is prior to their 19<sup>th</sup> birthday at the time of this authority application, **AND**
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday (SMA type IIIB/IIIC).

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment for untreated disease - prescribe up to 3 repeat prescriptions to enable dosing occurring at days: 0 (original prescription), 14 (repeat 1), 28 (repeat 2), 63 (repeat 3) (i.e. the loading doses); OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access) - prescribe zero repeat prescriptions where loading doses are complete, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Any active denervation or chronic neurogenic changes found on electromyography,
- (vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,
- (2) which of the above (i to vi) (at least 1) were present after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Changing the prescribed therapy

**Treatment criteria:**

- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19<sup>th</sup> birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- Patient must be untreated with gene therapy, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The prescriber has given consideration to whether a 'wash out' period is recommended or not prior to changing the prescribed therapy.

**Note** Subsequent changes in the prescribed drug where applicable are to occur under the 'Continuing treatment' phase listing of the drug that therapy is changing to.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**nusinersen 12 mg/5 mL intrathecal injection, 5 mL vial**

13083N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	3	..	104500.00	Spinraza [BD]

▪ **ONASEMNOGENE ABEPARVOVEC**

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

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

**Note** Special Pricing Arrangements apply.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Other disease modifying therapies for this condition are: (i) nusinersen, (ii) risdiplam.

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Accredited treatment centres and suppliers are those organisations accredited by the Gene Technology Regulator under section 92 of the **Gene Technology Act 2000**.

The following website provides a list of accredited organisations and may update without notice:

<https://www.ogtr.gov.au/what-weve-approved/accredited-organisations>

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Use in a patient untreated with disease modifying therapies for this condition

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs/symptoms of Type 1 SMA specified below; OR
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of: (i) nusinersen, (ii) risdiplam.

**Population criteria:**

- Patient must be no older than 9 months of age, **AND**
- Patient must have symptomatic Type 1 SMA; OR
- Patient must have pre-symptomatic SMA.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribing Instructions:

In the relevant PBS Authority Application form, specify the following:

(i) the SMA type being treated: symptomatic Type 1 SMA, or, pre-symptomatic SMA;

(ii) for Type 1 SMA, the signs/symptoms that the patient has experienced, together with the patient's age at the onset of these signs/symptoms.

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:

(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or

(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.

If the condition is pre-symptomatic SMA, confirm that there is genetic test finding that substantiates the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).

Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.

Defined signs and symptoms of type I SMA are:

- Onset before 6 months of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)

**Clinical criteria:**

- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.

**Treatment criteria:**

- Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.

**Population criteria:**

- Patient must be no older than 9 months of age, **AND**
- Patient must have symptomatic Type 1 SMA; OR

## MUSCULO-SKELETAL SYSTEM

- Patient must have pre-symptomatic SMA with 1-2 copies of SMN2 gene.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for one of the following:

- (i) Symptomatic Type 1 SMA; or
- (ii) Pre-symptomatic SMA with 1-2 copies of SMN2 gene.

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials

12961E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials

12971Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials

12974W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials

12949M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparovvec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack

12958B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparovvec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack

12940C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials

12957Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparovvec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack

12950N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparovvec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack

12963G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparovvec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack

12941D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparovvec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack

12952Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

### onasemnogene abeparovvec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparovvec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack

12955W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack**

12951P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack**

12977B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack**

12942E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack**

12976Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack**

12975X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack**

12956X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack**

12964H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials**

12962F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials**

12973T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials**

12954T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**■ ONASEMNOGENE ABEPARVOVEC**

**Note** Other disease modifying therapies for this condition are: (i) nusinersen, (ii) risdiplam.

**Note** Recognised hospitals in the management of SMA are Queensland Children's Hospital (Brisbane), Royal Children's Hospital Melbourne, Monash Children's Hospital (Melbourne), John Hunter Hospital (Newcastle), Sydney Children's Hospital Randwick, Children's Hospital at Westmead, Adelaide Women and Children's Hospital and Perth Children's Hospital.

**Note** Accredited treatment centres and suppliers are those organisations accredited by the Gene Technology Regulator under section 92 of the **Gene Technology Act 2000**.

The following website provides a list of accredited organisations and may update without notice:

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**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Use in a patient untreated with disease modifying therapies for this condition

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must not be undergoing treatment with this pharmaceutical benefit through this listing where prior treatment has occurred with any of: (i) nusinersen, (ii) risdiplam.

**Population criteria:**

- Patient must be no older than 9 months of age.

The authority application must be made in writing and must include:

(1) details of the proposed prescription; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Confirm that genetic testing has been completed to demonstrate the following in support of an SMA diagnosis:

(i) 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; or

(ii) deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variance in the remaining single copy of the SMN1 gene.

Confirm that there is a genetic test finding that substantiates the number of SMN2 gene copies to be 3 and has been determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA).

Quote the date, pathology provider name and any unique identifying serial number/code that links the genetic test result to the patient.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Use occurring after treatment with at least one disease modifying therapy for this condition (i.e. switching from nusinersen/risdiplam to onasemnogene abeparvovec)

**Clinical criteria:**

- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes.

**Treatment criteria:**

- Patient must be undergoing treatment with this pharmaceutical benefit following prior PBS-subsidised treatment with at least one other disease modifying therapy for this condition, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA; or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic of a recognised hospital in the management of SMA, **AND**
- Must be treated in a treatment centre that is each of: (i) recognised in the management of SMA, (ii) accredited in the use of this gene technology by the relevant authority, (iii) will(has) source(d) this product from an accredited supplier, as specified in the administrative notes to this listing, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit once only in a lifetime, **AND**
- Patient must be undergoing treatment with this pharmaceutical benefit with the intent that treatment with the replaced disease modifying agent is/has ceased.

**Population criteria:**



- Patient must be no older than 9 months of age, **AND**
- Patient must have pre-symptomatic SMA with 3 copies of the SMN2 gene.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for pre-symptomatic SMA with 3 copies of SMN2 gene.

State the weight of the patient in kilograms and request the appropriate product pack presentation with respect to the mix of 5.5 mL and 8.3 mL vials.

Adhere to any Product Information or local treatment guidelines with respect to treatment-free ('wash out') periods prior to administering this benefit.

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 3 x 8.3 mL vials**

13678X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 4 x 8.3 mL vials**

13665F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 8 x 8.3 mL vials**

13673P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 9 x 8.3 mL vials**

13676T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack**

13669K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack**

13682D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 2 x 8.3 mL vials**

13674Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack**

13683E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack**

13681C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack**

13679Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack**

13668J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 5.5 mL vials] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8.3 mL vial], 1 pack**

13663D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [2 x 8.3 mL vials], 1 pack**

13671M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [3 x 8.3 mL vials], 1 pack**

13670L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [4 x 8.3 mL vials], 1 pack**

13672N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5 x 8.3 mL vials], 1 pack**

13680B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [6 x 8.3 mL vials], 1 pack**

13677W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [7 x 8.3 mL vials], 1 pack**

13662C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection [5.5 mL vial] (&) onasemnogene abeparvovec 20 trillion vector genomes/mL injection [8 x 8.3 mL vials], 1 pack**

13666G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 5 x 8.3 mL vials**

13667H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 6 x 8.3 mL vials**

13664E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

**onasemnogene abeparvovec 20 trillion vector genomes/mL injection, 7 x 8.3 mL vials**

13675R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	2527773.87	Zolgensma [NV]

▪ **RISDIPLAM**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene;  
 OR

HSD (Public)

- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must have experienced at least two of the defined signs and symptoms of SMA type I, II or IIIa prior to 3 years of age, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic.

**Clinical criteria:**

- Patient must be untreated with gene therapy.

**Population criteria:**

- Patient must be 18 years of age or under.

Defined signs and symptoms of type I SMA are:

- Onset before 6 months of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type II SMA are:

- Onset between 6 and 18 months; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Weakness in trunk righting/derotation; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Defined signs and symptoms of type IIIa SMA are:

- Onset between 18 months and 3 years of age; and
- Failure to meet or regression in ability to perform age-appropriate motor milestones; or
- Proximal weakness; or
- Hypotonia; or
- Absence of deep tendon reflexes; or
- Failure to gain weight appropriate for age; or
- Any active chronic neurogenic changes; or
- A compound muscle action potential below normative values for an age-matched child.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Application for authorisation of initial treatment must be in writing and must include:

- a completed authority prescription form; and
- a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
  - specification of SMA type (I, II or IIIa); and
  - sign(s) and symptom(s) that the patient has experienced; and
  - patient's age at the onset of sign(s) and symptom(s).

The approved Product Information recommended dosing is as follows:

- 16 days to less than 2 months of age: 0.15 mg/kg
- 2 months to less than 2 years of age: 0.20 mg/kg
- 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

12614X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	10841.89	Evrysdi [RO]

▪ **RISDIPLAM**

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

**Population criteria:**

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

14646W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	10841.89	Evrysdi [RO]

▪ **RISDIPLAM**

**Note** The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment with this drug of either symptomatic Type I, II or IIIa SMA, or, pre-symptomatic SMA (1 or 2 copies of the SMN2 gene)

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition; OR
- Patient must be eligible for continuing PBS-subsidised treatment with nusinersen for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition, **AND**

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug, **AND**
- The treatment must be given concomitantly with best supportive care for this condition.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must not be undergoing treatment through this 'Continuing treatment' listing where the most recent PBS authority approval for this PBS indication has been for gene therapy.

**Population criteria:**

- Patient must have been 18 years of age or younger at the time of initial treatment with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

In a patient who wishes to switch from PBS-subsidised nusinersen to PBS-subsidised risdiplam for this condition a wash out period may be required.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- 16 days to less than 2 months of age: 0.15 mg/kg
- 2 months to less than 2 years of age: 0.20 mg/kg
- 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

12606L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	10841.89	Evrysdi [RO]

**▪ RISDIPLAM**

**Note** For the next authority application after this application, continue treatment through the 'Treatment phase: Continuing treatment' under the indication: 'Symptomatic Type I, II or IIIa spinal muscular atrophy (SMA)'.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment occurring after onasemnogene abeparvovec therapy in a patient with Type 1 SMA

**Clinical criteria:**

- Patient must have experienced a regression in a developmental state listed below (see 'Definition') despite treatment with gene therapy - confirm that this: (i) not due to an acute concomitant illness; (ii) not due to non-compliance to best-supportive care, (iii) apparent for at least 3 months, (iv) verified by another clinician in the treatment team - state the full name of this clinician plus their profession (e.g. medical practitioner, nurse, physiotherapist; this is not an exhaustive list of examples), **AND**
- The treatment must not be a PBS-subsidised benefit where the condition has progressed to a point where invasive permanent assisted ventilation (i.e. ventilation via tracheostomy tube for at least 16 hours per day) is required in the absence of potentially reversible causes, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- The treatment must not be in combination with PBS-subsidised treatment with nusinersen for this condition.

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, or in consultation with a specialist medical practitioner experienced in the diagnosis and management of SMA associated with a neuromuscular clinic, **AND**
- Patient must be undergoing treatment under this Treatment phase listing once only - for continuing treatment beyond this authority application, refer to the drug's relevant 'Continuing treatment' listing for the patient's SMA type.

**Population criteria:**

- Patient must have a prior authority approval for any drug PBS-listed for symptomatic Type 1 SMA, with at least one approval having been for gene therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Do not resubmit previously submitted documentation concerning the diagnosis and type of SMA.

Confirm that a previous PBS authority application has been approved for symptomatic Type 1 SMA.

Definition:

Various childhood developmental states (1 to 9) are listed below, some followed by further observations (a up to d). Where at least one developmental state/observation is no longer present, that developmental state has regressed.

0. Absence of developmental states (1 to 9) listed below:

1. Rolls from side to side on back;
2. Child holds head erect for at least 3 seconds unsupported;
3. Sitting, but with assistance;
4. Sitting without assistance:

- (a) Child sits up straight with the head erect for at least 10 seconds;
- (b) Child does not use arms or hands to balance body or support position.

5. Hands and knees crawling:

- (a) Child alternately moves forward or backwards on hands and knees;
- (b) The stomach does not touch the supporting surface;
- (c) There are continuous and consecutive movements at least 3 in a row.

6. Standing with assistance:

- (a) Child stands in upright position on both feet, holding onto a stable object (e.g. furniture) with both hands and without leaning on object;
- (b) The body does not touch the stable object, and the legs support most of the body weight;
- (c) Child thus stands with assistance for at least 10 seconds.

7. Standing alone:

- (a) Child stands in upright position on both feet (not on the toes) with the back straight;
- (b) The leg supports 100% of the child's weight;
- (c) There is no contact with a person or object;
- (d) Child stands alone for at least 10 seconds.

8. Walking with assistance:

- (a) Child is in an upright position with the back straight;
- (b) Child makes sideways or forced steps by holding onto a stable object (e.g. furniture) with 1 or both hands;
- (c) One leg moves forward while the other supports part of the body weight;
- (d) Child takes at least 5 steps in this manner.

9. Walking alone:

- (a) Child takes at least 5 steps independently in upright position with the back straight;
- (b) One leg moves forward while the other supports most of the body weight;
- (c) There is no contact with a person or object.

Confirm which developmental state has regressed by: (i) stating the overall developmental state (1 - 9) the patient was in at the time of gene therapy, or, the best developmental state achieved since gene therapy, and (ii) stating the patient's current overall developmental state (i.e. a number that is lower than stated in (i)).

Where the patient has neither regressed from a developmental state nor reached the next developmental state, PBS-subsidy of this benefit is not available.

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

12943F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	10841.89	Evrysdi [RO]

▪ **RISDIPLAM**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment with this drug of pre-symptomatic spinal muscular atrophy (SMA)

#### **Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA.

#### **Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must have genetic confirmation that there are 1 to 2 copies of the survival motor neuron 2 (SMN2) gene, **AND**

- The condition must be pre-symptomatic, **AND**

- The treatment must be given concomitantly with best supportive care for this condition, **AND**

- Patient must be untreated with gene therapy.

#### **Population criteria:**

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

(a) details of the proposed prescription; and

(b) a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:

(i) confirmation of genetic diagnosis of SMA; and

(ii) a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

(i) 16 days to less than 2 months of age: 0.15 mg/kg

(ii) 2 months to less than 2 years of age: 0.20 mg/kg

(iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg

(iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

1 unit where (i) applies;

2 units where (ii) applies;

3 units where (iii) applies;

3 units where (iv) applies.

#### **risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

13655Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	10841.89	Evrysdi [RO]

#### ▪ **RISDIPLAM**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Pre-symptomatic spinal muscular atrophy (SMA)

Treatment Phase: Initial treatment of pre-symptomatic spinal muscular atrophy (SMA) with 3 copies of the SMN2 gene

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA.

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- The condition must be pre-symptomatic SMA, with genetic confirmation that there are 3 copies of the survival motor neuron 2 (SMN2) gene, **AND**
- The treatment must be given concomitantly with best supportive care for this condition, **AND**
- Patient must be untreated with gene therapy.

**Population criteria:**

- Patient must be aged under 36 months prior to commencing treatment.

Application for authorisation of initial treatment must be in writing (lodged via postal service or electronic upload) and must include:

- details of the proposed prescription; and
- a completed Spinal muscular atrophy PBS Authority Application Form which includes the following:
  - confirmation of genetic diagnosis of SMA; and
  - a copy of the results substantiating the number of SMN2 gene copies determined by quantitative polymerase chain reaction (qPCR) or multiple ligation dependent probe amplification (MLPA)

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- 16 days to less than 2 months of age: 0.15 mg/kg
- 2 months to less than 2 years of age: 0.20 mg/kg
- 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

14659M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	..	..	10841.89	Evrysdi [RO]

▪ **RISDIPLAM**

**Note** The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

- Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions
- Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions
- Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions
- Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions
- Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in a child or adult, but where treatment was initiated during childhood

**Treatment criteria:**

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; OR
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated prior to the patient's 19<sup>th</sup> birthday for SMA type IIIB/IIIC, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

HSD (Public)



**Clinical criteria:**

- The treatment must be ceased when invasive permanent assisted ventilation is required in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

13631K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±3	5	..	*32525.67	Evrysdi [RO]

**■ RISDIPLAM**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in an adult who did not initiate PBS subsidy with this drug during childhood

**Population criteria:**

- Patient must be at least 19 years of age at the time of this authority application, but never claimed PBS subsidy for a disease modifying treatment during childhood, **AND**
- Patient must have SMA where the onset of signs/symptoms (at least one) of SMA first occurred prior to their 19<sup>th</sup> birthday (SMA symptom onset after this age will be considered type IV SMA, which is not PBS-subsidised).

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Failure to gain weight appropriate for age,
- (vi) Any active denervation or chronic neurogenic changes found on electromyography,
- (vii) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of childhood onset spinal muscular atrophy,
- (2) which of the above (i to vii) (at least 1) were present during childhood,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

13654P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±3	7	..	*32525.67	Evrysdi [RO]

▪ **RISDIPLAM**

**Note** Literature references for various instruments measuring motor function and quality of life in the context of spinal muscular atrophy are:

Revised Upper Limb Module

Mazzone et al. 2017. Revised upper limb module for spinal muscular atrophy: Development of a new module. **Muscle & Nerve** 55(6):869-874

Hammersmith Functional Motor Scale - Expanded

Ramsey et al. 2017. Revised Hammersmith Scale for spinal muscular atrophy: A SMA specific clinical outcome assessment tool. **PLoS ONE** 12(2): e0172346. doi:10.1371/journal.pone.0172346.

6-Minute Walk Test (6MWT)

American Thoracic Society. 2002. ATS statement: Guidelines for the six-minute walk test. **American Journal of Respiratory and Critical Care Medicine** 166(1), pp 111-117

The National Health Foundation of Australia has 6MWT test standardised instructions and recording forms located at: <https://www.hearionline.org.au/resources/documents-and-links#exercise>

SMA Health Index

Zizzi et al. 2021. The Spinal Muscular Atrophy Health Index (SMA-HI): A Novel Outcome for Measuring How a Patient Feels and Functions. **Muscle & Nerve** 63(10), pp 837-844

SMA Functional Rating Scale

Elsheikh et al. 2018. Reliability of Spinal Muscular Atrophy Functional Rating Scale (SMAFRS) in Ambulatory Adults with Spinal Muscular Atrophy. **Neurology** April (15 Supplement) P4.452

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Spinal muscular atrophy (SMA)

Treatment Phase: Continuing/maintenance treatment in an adult where treatment was initiated in adulthood

**Treatment criteria:**

- Patient must be undergoing continuation of existing PBS-subsidised treatment with this drug; OR
- Patient must be undergoing a change in prescribed SMA drug to this drug - the drug treatment being replaced was a PBS benefit initiated after the patient's 19<sup>th</sup> birthday, **AND**
- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- The treatment must be each of: (i) occurring from week 104 onwards relative to the first administered dose, (ii) demonstrating a clinically meaningful response; OR
- The treatment must be occurring within the first 104 weeks from the first administered dose, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

Where this authority application seeks to continue treatment beyond the first 104 weeks of treatment, comprehensive assessment must be undertaken periodically and documented, involving the patient and the treating physician to establish agreement that treatment is continuing to produce a clinically meaningful response.

A clinically meaningful response is present where an improvement, stabilisation or minimal decline in symptoms has occurred as a result of this drug treatment and where there is agreement between the treating physician and patient over what constitutes improvement, stabilisation, or minimal decline.

PBS subsidy must cease if there is no agreement on whether a clinically meaningful response is present.

Undertake re-assessments for a clinically meaningful response at least every six months. Document these re-assessments in the patient's medical records.

In undertaking comprehensive assessments, where practical, a clinically meaningful response assessment encompasses the patient's motor function as assessed using an instrument like the Revised Upper Limb Module (RULM), Hammersmith Functional Motor Scale - Expanded (HFMSSE) or 6-minute walk test (6MWT), and the patient's quality of life including, but not limited to, level of independence. Quality of life may be informed by use of the SMA Health Index (SMA-HI) or SMA Functional Rating Scale (SMAFRS).

**risdiplam 750 microgram/mL powder for oral liquid, 80 mL**

13656R	Max. Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±3	5	..	*32525.67	Evrysdi [RO]

▪ **RISDIPLAM**

**Note** The maximum quantity of drug to be subsidised per dispensing, as well as the number of repeat prescriptions is to be as follows:

Patient weight greater than 19 kg: up to 3 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 17 kg to 19 kg: up to 3 units per dispensing, with up to 4 repeat prescriptions

Patient weight between 13 kg to 17 kg: up to 2 units per dispensing, with up to 5 repeat prescriptions

Patient weight between 10 kg up to 13 kg: up to 2 units per dispensing, with up to 4 repeat prescriptions

Patient weight less than 10 kg: up to 1 unit per dispensing, with up to 5 repeat prescriptions

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** An outcome on the authority application is not immediate, but will follow in due course. Electronic upload is encouraged to reduce processing time.

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Symptomatic type IIIB/IIIC spinal muscular atrophy (SMA)

Treatment Phase: Initial PBS-subsidised treatment with this drug in a child

**Population criteria:**

- Patient must be of an age that is prior to their 19<sup>th</sup> birthday at the time of this authority application, **AND**
- Patient must have SMA type III where the onset of signs/symptoms of SMA first occurred after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday (SMA type IIIB/IIIC).

**Treatment criteria:**

- Must be treated by a specialist medical practitioner experienced in the diagnosis/management of SMA; OR
- Must be treated by a medical practitioner who has been directed to prescribe this benefit by a specialist medical practitioner experienced in the diagnosis/management of SMA, **AND**
- Patient must be undergoing initial PBS-subsidised treatment with this drug for untreated disease; OR
- Patient must be undergoing initial PBS-subsidised treatment, but the patient has initiated treatment via non-PBS supply (e.g. clinical trial, sponsor compassionate access), **AND**
- Patient must be undergoing concomitant treatment with best supportive care, but this benefit is the sole PBS-subsidised disease modifying treatment.

**Clinical criteria:**

- The condition must have genetic confirmation of 5q homozygous deletion of the survival motor neuron 1 (SMN1) gene; OR
- The condition must have genetic confirmation of deletion of one copy of the SMN1 gene in addition to a pathogenic/likely pathogenic variant in the remaining single copy of the SMN1 gene, **AND**
- Patient must not be receiving invasive permanent assisted ventilation in the absence of a potentially reversible cause while being treated with this drug.

Invasive permanent assisted ventilation means ventilation via tracheostomy tube for greater than or equal to 16 hours per day.

The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Signs and symptoms of spinal muscular atrophy in the context of this PBS restriction are:

## NERVOUS SYSTEM

- (i) Failure to meet or regression in ability to perform age-appropriate motor milestones,
- (ii) Proximal weakness,
- (iii) Hypotonia,
- (iv) Absence of deep tendon reflexes,
- (v) Any active denervation or chronic neurogenic changes found on electromyography,
- (vi) A compound muscle action potential below normative values for an age-matched child.

In this authority application, confirm:

- (1) the patient's medical history is consistent with a diagnosis of type IIIB/IIIC spinal muscular atrophy,
- (2) which of the above (i to vi) (at least 1) were present after their 3<sup>rd</sup> birthday, but before their 19<sup>th</sup> birthday,
- (3) the age of the patient (rounded to the nearest year) when the first sign/symptom was observed.

The quantity of drug and number of repeat prescriptions prescribed is to be in accordance with the relevant 'Note' attached to this listing.

The approved Product Information recommended dosing is as follows:

- (i) 16 days to less than 2 months of age: 0.15 mg/kg
- (ii) 2 months to less than 2 years of age: 0.20 mg/kg
- (iii) 2 years of age and older weighing less than 20 kg: 0.25 mg/kg
- (iv) 2 years of age and older weighing 20 kg or more: 5 mg

In this authority application, state which of (i) to (iv) above applies to the patient. Based on (i) to (iv), prescribe up to:

- 1 unit where (i) applies;
- 2 units where (ii) applies;
- 3 units where (iii) applies;
- 3 units where (iv) applies.

### risdiplam 750 microgram/mL powder for oral liquid, 80 mL

13633M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±3	5	..	*32525.67	Evrysdi [RO]

## NERVOUS SYSTEM

## ANTI-PARKINSON DRUGS

### DOPAMINERGIC AGENTS

*Dopa and dopa derivatives*

### LEVODOPA + CARBIDOPA

**Note** Special Pricing Arrangements apply.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

#### Authority required (STREAMLINED)

**10138**

Advanced Parkinson disease

#### **Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic.

### levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

11913B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*5768.00	Duodopa [VE]

### LEVODOPA + CARBIDOPA

**Note** Special Pricing Arrangements apply.

**Note** Patients should have adequate cognitive function to manage administration with a portable continuous infusion pump.

#### Authority required (STREAMLINED)

**10375**

Advanced Parkinson disease

#### **Clinical criteria:**

- Patient must have severe disabling motor fluctuations not adequately controlled by oral therapy, **AND**
- The treatment must be commenced in a hospital-based movement disorder clinic, **AND**
- Patient must require continuous administration of levodopa without an overnight break; OR
- Patient must require a total daily dose of more than 2000 mg of levodopa.

### levodopa 20 mg/mL + carbidopa monohydrate 5 mg/mL intestinal gel, 7 x 100 mL

9743T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	8	5	..	*11536.00	Duodopa [VE]

*Dopamine agonists*

### APOMORPHINE

#### Authority required (STREAMLINED)

**10863**

Parkinson disease

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 100 mg/20 mL injection, 5 x 20 mL vials**

11093W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	18	5	..	*7427.34	Apomine Solution for Infusion [IT]

■ **APOMORPHINE****Authority required (STREAMLINED)****11385**

Parkinson disease

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 50 mg/5 mL injection, 5 x 5 mL ampoules**

5610G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*6029.64	Movapo [TD]

**apomorphine hydrochloride hemihydrate 50 mg/10 mL injection, 5 x 10 mL syringes**

10950H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	36	5	..	*8017.20	Movapo PFS [TD]

■ **APOMORPHINE****Note** No increase in the maximum quantity or number of units may be authorised.**Note** Pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL pen device and pharmaceutical benefits that have the form apomorphine injection 30 mg/3 mL cartridge are equivalent for the purposes of substitution.**Authority required (STREAMLINED)****10863**

Parkinson disease

**Clinical criteria:**

- Patient must have experienced severely disabling motor fluctuations which have not responded to other therapy, **AND**
- The treatment must be commenced in a specialist unit in a hospital setting.

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL cartridges**

11672H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2588.00	<sup>a</sup> Apomine Intermittent [IT]

**apomorphine hydrochloride hemihydrate 30 mg/3 mL injection, 5 x 3 mL pen devices**

11477C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	20	5	..	*2588.00	<sup>a</sup> Movapo Pen [TD]

■ **PSYCHOLEPTICS****ANTIPSYCHOTICS***Diazepines, oxazepines, thiazepines and oxepines*■ **CLOZAPINE****Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.**Authority required (STREAMLINED)****5015**

Schizophrenia

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

**Clinical criteria:**

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

## NERVOUS SYSTEM

### clozapine 50 mg/mL oral liquid, 100 mL

11433R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	‡1	..	..	135.00	Versacloz [PF]

### ■ CLOZAPINE

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS), Pfizer ClopineCentral or Juno Connected Clozitor.

#### **Authority required (STREAMLINED)**

#### **5015**

Schizophrenia

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a psychiatrist or in consultation with the psychiatrist affiliated with the hospital or specialised unit managing the patient.

#### **Clinical criteria:**

- Patient must be non-responsive to other neuroleptic agents; OR
- Patient must be intolerant of other neuroleptic agents.

Patients must complete at least 18 weeks of initial treatment under this restriction before being able to qualify for treatment under the continuing restriction.

The name of the consulting psychiatrist should be included in the patient's medical records.

A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

### clozapine 50 mg/mL oral liquid, 100 mL

5630H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	135.00	Clopine Suspension [PF]

### clozapine 100 mg tablet, 100

5629G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*208.08	Clopine 100 [PF] Clozitor [JU]	Clozaril 100 [GO]

### clozapine 200 mg tablet, 100

5627E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*416.16	Clopine 200 [PF]	Clozitor [JU]

### clozapine 25 mg tablet, 100

5628F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*55.50	Clopine 25 [PF] Clozitor [JU]	Clozaril 25 [GO]

### clozapine 50 mg tablet, 100

5626D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*110.98	Clopine 50 [PF]	Clozitor [JU]

## ■ OTHER NERVOUS SYSTEM DRUGS

### OTHER NERVOUS SYSTEM DRUGS

*Other nervous system drugs*

### ■ PATISIRAN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Hereditary transthyretin amyloidosis

Treatment Phase: Initial treatment

**Population criteria:**

- Patient must have either: (i) stage 1 polyneuropathy, (ii) stage 2 polyneuropathy.

**Clinical criteria:**

- Patient must not have previously received PBS-subsidised treatment with this drug for this PBS indication.

**Population criteria:**

- Patient must be at least 18 years of age.

**Clinical criteria:**

- The condition must be hereditary transthyretin amyloidosis confirmed by genetic testing, **AND**
- Patient must have a Polyneuropathy Disability (PND) score description of either I, II, IIIA, IIIB; OR
- Patient must have a Familial Amyloid Polyneuropathy (FAP) stage description of 1 or 2, **AND**
- Patient must not have previously undergone a liver transplant, **AND**
- Patient must not exhibit heart failure symptoms (defined as New York Heart Association NYHA class III or IV).

**Treatment criteria:**

- Must be treated by a consultant with experience in the management of amyloid disorders or in consultation with a consultant with experience in the management of amyloid disorders, **AND**
- Patient must be undergoing treatment with this drug as a monotherapy (i.e. not in combination with any other disease modifying medicines for amyloidosis disorders).

PND scores in the context of this PBS restriction are:

Stage 0 - No symptoms;

Stage I - Sensory disturbances but preserved walking capability;

Stage II - Impaired walking capacity but able to walk without stick or crutches;

Stage IIIA - Walking with help of one stick or crutch;

Stage IIIB - Walking with help of two sticks or crutches;

Stage IV - Confined to wheelchair or bedridden.

FAP stage in the context of this PBS restriction are:

Stage 0 - No symptoms;

Stage 1 - Unimpaired ambulation;

Stage 2 - Assistance with ambulation required;

Stage 3 - Wheelchair-bound or bedridden.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Hereditary transthyretin amyloidosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must continue to demonstrate clinical benefit, **AND**
- Patient must not be permanently bedridden; OR
- Patient must not be receiving end-of-life care.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Authority required**

Hereditary transthyretin amyloidosis

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

**Clinical criteria:**

- Patient must have received treatment with this drug for this condition prior to 1 August 2024, **AND**
- Patient must continue to demonstrate clinical benefit, **AND**
- Patient must not be permanently bedridden; OR
- Patient must not be receiving end-of-life care.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail.

If the application is submitted through HPOS form upload or mail, it must include:

(a) details of the proposed prescription; and

(b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**patisiran 10 mg/5 mL injection, 5 mL vial**

14264R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	7	..	*37349.79	Onpatro [WM]

RESPIRATORY SYSTEM  
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES  
OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES  
*Other systemic drugs for obstructive airway diseases*

**BENRALIZUMAB**

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.



(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Balance of supply

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

#### **benralizumab 30 mg/mL injection, 1 mL pen device**

12000N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	3145.45	Fasenra Pen [AP]

### ▪ BENRALIZUMAB

#### **Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to

ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialed it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omaliuzumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omaliuzumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omaliuzumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

- (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

- (a) if applicable, details of maintenance oral corticosteroid dose; and
- (b) a completed Asthma Control Questionnaire (ACQ-5) score.

### benralizumab 30 mg/mL injection, 1 mL pen device

11995H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	3145.45	Fasenra Pen [AP]

## ■ BENRALIZUMAB

### Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ, please contact AstraZeneca Medical Information on 1800 805 342.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR

- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course of benralizumab sufficient for up to 32 weeks of therapy, at a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and
- (b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) the eosinophil count and date; and
- (e) Asthma Control Questionnaire (ACQ-5) score.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 4 repeats to provide for an initial course sufficient for up to 32 weeks of therapy, based on a dose of 30 mg every 4 weeks for the first three doses (weeks 0, 4, and 8) then 30 mg every eight weeks thereafter (refer to the TGA-approved Product Information).

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- details of the proposed prescription; and
- a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- details (date and duration of treatment) of prior biological medicine treatment; and
- eosinophil count and date; and
- if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

**benralizumab 30 mg/mL injection, 1 mL pen device**

11994G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	4	..	3145.45	Fasenra Pen [AP]

▪ **DUPIUMAB**

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to

an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omaliuzumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omaliuzumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omaliuzumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or [MedInfo.Australia@sanofi.com](mailto:MedInfo.Australia@sanofi.com)

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

**Authority required**

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

**Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,  
OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and, for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

- (a) if applicable, details of maintenance oral corticosteroid dose; and
- (b) a completed Asthma Control Questionnaire (ACQ-5) score.

**dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes**

12302L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1609.86	Dupixent [SW]

**dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes**

12318H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1609.86	Dupixent [SW]

■ **DUPILUMAB**

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as



long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

## **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

## **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

## **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have been receiving regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation, **AND**
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

## **Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes:

- (i) Adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated; **AND**
- (ii) treatment with oral corticosteroids as outlined in the clinical criteria.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and

(ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and
- (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) Asthma Control Questionnaire (ACQ-5) score; and
- (e) if applicable, the eosinophil count and date; and
- (f) if applicable, the IgE result and date.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have each of: (i) total serum human immunoglobulin E of at least 30 IU/mL measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, (ii) past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have received regular maintenance oral corticosteroids (OCS) in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

#### **Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy at a dose of 600 mg as an initial dose, followed by 300 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- (b) details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and
- (c) if applicable, the eosinophil count and date; and
- (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- (e) if applicable, the IgE result and date; and
- (f) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

**dupilumab 300 mg/2 mL injection, 2 x 2 mL syringes**

12293B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	8	..	1609.86	Dupilent [SW]

▪ **DUPILUMAB**

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted

with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or

(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Sanofi Medical Information on 1800 818 806 or MedInfo.Australia@sanofi.com

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment 1 - (New patient; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months; OR
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured in the last 12 months that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**

- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, **OR** 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and
- (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) Asthma Control Questionnaire (ACQ-5) score; and
- (e) if applicable, the eosinophil count and date; and
- (f) if applicable, the IgE result and date.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

**Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have had a total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, that has past or current evidence of atopy, documented by either: (i) skin prick testing; (ii) an in vitro measure of specific IgE, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment at around 28 weeks, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request up to 8 repeats to provide for an initial course of dupilumab sufficient for up to 32 weeks of therapy, at a dose of 400 mg as an initial dose, followed by 200 mg every 2 weeks thereafter.

A swapping between 200 mg and 300 mg strengths is not permitted as the respective strengths are PBS approved for different patient cohorts.

A multidisciplinary severe asthma clinic team comprises of:

- A respiratory physician; and
- A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- details (treatment, date of commencement, duration of therapy) of prior biological medicine treatment; and
- if applicable, the eosinophil count and date; and
- if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- if applicable, the IgE result and date; and
- the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

**dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL syringes**

12309W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	8	..	1609.86	Dupixent [SW]

▪ **MEPOLIZUMAB**

**Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Balance of supply

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**



- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.

### mepolizumab 100 mg/mL injection, 1 mL pen device

12021Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	1556.10	Nucala [GK]

## ■ MEPOLIZUMAB

### Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

## **Authority required**

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

### **Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to this biological medicine is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline,

OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5.

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment or the assessment of oral corticosteroid dose, should be made from 20 weeks after the first dose of PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate number of repeats to provide for a continuing course of this drug sufficient for up to 24 weeks of therapy.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following information must be provided at the time of application and must be documented in the patient's medical records:

- (a) if applicable, details of maintenance oral corticosteroid dose; and
- (b) a completed Asthma Control Questionnaire (ACQ-5) score.

### mepolizumab 100 mg/mL injection, 1 mL pen device

12064Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1556.10	Nucala [GK]

## ▪ MEPOLIZUMAB

### Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

#### (1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

#### (3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

#### (4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on

the PBS; and

(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ, please contact GlaxoSmithKline Medical Information on 1800 033 109.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have a blood eosinophil count of at least 300 cells per microlitre in the last 12 months; OR
- Patient must have blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

#### **Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

(a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, **AND**

(b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician.

The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course of mepolizumab sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details (treatment, date of commencement, duration of therapy) of prior optimised asthma drug therapy; and
- (b) if applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) the eosinophil count and date; and
- (e) Asthma Control Questionnaire (ACQ-5) score.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have had a blood eosinophil count of at least 300 cells per microlitre and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma; OR
- Patient must have had a blood eosinophil count of at least 150 cells per microlitre while receiving treatment with oral corticosteroids and that is no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

#### **Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for severe asthma who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. To avoid an interruption of supply for the first continuing treatment, the assessment should be provided no later than 2 weeks prior to the patient completing their current treatment course, unless the patient is currently on a treatment break. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

At the time of the authority application, medical practitioners should request up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- (b) details (date and duration of treatment) of prior biological medicine treatment; and
- (c) eosinophil count and date; and
- (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

## mepolizumab 100 mg/mL injection, 1 mL pen device

12007Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	1556.10	Nucala [GK]

### ▪ MEPOLIZUMAB

**Note** The length of a break in therapy is measured from the date that the relevant PBS-subsidised medicine listed for this PBS indication is ceased during the most recent treatment cycle, until the date of the subsequent application for treatment under a new treatment cycle.

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

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

**Note** Special Pricing Arrangements apply.

#### Authority required

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

#### **Clinical criteria:**

- Patient must have a diagnosis of CRSwNP confirmed by at least one of: (i) nasal endoscopy, (ii) computed tomography (CT) scan, with the results documented in the patient's medical records; OR
- Patient must have a diagnosis of CRSwNP from at least two physicians of the above mentioned prescriber types, **AND**
- Patient must have undergone surgery for the removal of nasal polyps; OR
- Patient must have the written advice from at least two physicians of the above mentioned prescriber types demonstrating inappropriateness for surgery, **AND**
- Patient must have, despite optimised nasal polyp therapy, at least two of: (i) bilateral endoscopic nasal polyp score of at least 5 (out of a maximum score of 8, with a minimum score of 2 in each nasal cavity), (ii) nasal obstruction visual analogue scale (VAS) score greater than 5 (out of a maximum score of 10), (iii) overall symptom VAS score greater than 7 (out of a maximum score of 10), **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for this condition; OR
- Patient must have had a 12 month break in PBS-subsidised treatment with a biological medicine for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for any of: (i) nasal polyps, (ii) uncontrolled severe allergic asthma, (iii) uncontrolled severe asthma, **AND**
- Patient must have failed to achieve adequate control with optimised nasal polyp therapy which has been documented, **AND**
- Patient must have blood eosinophil count greater than or equal to 300 cells per microlitre in the last 12 months.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Optimised nasal polyp therapy includes:

- (a) adherence to intranasal corticosteroid therapy for at least 2 months, unless contraindicated or not tolerated
- (b) if required, nasal irrigation with saline

Where the patient has a contraindication or intolerance to intranasal corticosteroid therapy, document the reasons for the contraindication or intolerance in the patient's medical file.

The authority application must be made in writing and must include:

- (a) a completed authority prescription form,
- (b) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice),
- (c) details (date of commencement and duration of therapy) of prior optimised nasal polyp medicine treatment,
- (d) details (date and treatment) of nasal polyp surgery; or
- (e) if applicable, details of surgical exception including serious comorbid disease (e.g. cardiovascular, stroke) making the risk of surgery unacceptable,
- (f) the eosinophil count and date,
- (g) two of the following, measured within the past 12 months: (i) baseline bilateral endoscopic nasal polyp score, (ii) baseline nasal obstruction VAS score, (iii) baseline overall VAS score.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

#### **Authority required**

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) ear nose and throat specialist (ENT), (v) general physician experienced in the management of patients with CRSwNP.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have both demonstrated and sustained an adequate response to this drug, defined as having at least one of: (i) an improvement in bilateral endoscopic nasal polyp score of at least 1.0 compared to the baseline level provided with the initial authority application, (ii) an improvement in nasal obstruction visual analogue scale (VAS) score of at least 3.0 compared to the baseline level provided with the initial authority application, (iii) an improvement in overall symptom VAS score of at least 2.5 compared to the baseline level provided with the initial authority application.

#### **Population criteria:**

- Patient must be at least 18 years of age.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **mepolizumab 100 mg/mL injection, 1 mL pen device**

13237Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	1556.10	Nucala [GK]

### ■ OMALIZUMAB

#### **Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under

the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

(1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
  - (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
  - (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].
- All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

(2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

(3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

(4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

## **Authority required**

Uncontrolled severe asthma

Treatment Phase: Balance of supply

## **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

## **Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or commencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; OR
- The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction.



**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

11846L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	107.60	Xolair [NV]

**omalizumab 150 mg/mL injection, 1 mL syringe**

11828M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	215.19	Xolair [NV]

**■ OMALIZUMAB****Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

Services Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Services Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

**Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Balance of supply in a patient aged 6 to 12 years

**Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

**Clinical criteria:**

- Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; OR
- Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment, **AND**
- The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction.

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

11962N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	107.60	Xolair [NV]

**omalizumab 150 mg/mL injection, 1 mL syringe**

11950Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	..	..	215.19	Xolair [NV]

## ■ OMALIZUMAB

### Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

#### (1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

#### (3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

#### (4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

#### (5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

#### (6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 12 years or older.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.

The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.

Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment.

A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

(a) Asthma Control Questionnaire (ACQ-5) score; and

(b) If applicable, maintenance oral corticosteroid dose; and

(c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.

#### **omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

11835X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	107.60	Xolair [NV]

#### **omalizumab 150 mg/mL injection, 1 mL syringe**

11824H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	215.19	Xolair [NV]

## **■ OMALIZUMAB**

### **Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment

with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

(1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

(2) Baseline measurements to determine response:

Services Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Services Australia will assess response according to these revised baseline measurements.

(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

#### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have a documented history of severe allergic asthma, **AND**
- Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction.

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

An adequate response to omalizumab treatment is defined as:

(a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR

(b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR

(c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.

A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.

Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.

The following information must be provided at the time of application and must be documented in the patient's medical records:

- (a) If applicable, the baseline and maintenance oral corticosteroid dose; and
- (b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or
- (c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and
- (d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.

The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.

#### omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

11946R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	107.60	Xolair [NV]

#### omalizumab 150 mg/mL injection, 1 mL syringe

11945Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	215.19	Xolair [NV]

### ■ OMALIZUMAB

#### Note TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.

A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.

A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.

Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.

Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.

#### (1) Initial treatment:

Applications for initial treatment should be made where:

- (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or
- (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or
- (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].

All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

#### (2) Continuing treatment:

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

#### (3) Baseline measurements to determine response:

Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.

For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.

However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.

#### (4) Swapping therapy within the same treatment cycle.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction.

However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle.

Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:

- (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or
- (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and
- (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.

(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy:

A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.

(6) Monitoring of patients:

Omalizumab only:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

## **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)

## **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

## **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; OR
- Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma, **AND**
- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; OR
- Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**
- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

## **Population criteria:**

- Patient must be aged 12 years or older.

Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND
- (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug.

If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle.

A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle.

The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.

There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and
- (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and
- (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (d) the IgE result and date; and
- (e) Asthma Control Questionnaire (ACQ-5) score.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

#### **Authority required**

Uncontrolled severe asthma

Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months; OR
- Patient must have been diagnosed by a multidisciplinary severe asthma clinic team, **AND**
- Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle, **AND**
- Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle, **AND**
- Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma, **AND**
- Patient must not receive more than 32 weeks of treatment under this restriction, **AND**

- The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma.

**Population criteria:**

- Patient must be aged 12 years or older.

An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.

An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.

This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.

At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.

A multidisciplinary severe asthma clinic team comprises of:

- (i) A respiratory physician; and
- (ii) A pharmacist, nurse or asthma educator.

The authority application must be made in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and
- (b) details (date and duration of treatment) of prior biological medicine treatment; and
- (c) the IgE results and date; and
- (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and
- (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

**omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe**

10118M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	107.60	Xolair [NV]

**omalizumab 150 mg/mL injection, 1 mL syringe**

10109C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	7	..	215.19	Xolair [NV]

**■ OMALIZUMAB**

**Note TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA**

Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction.

Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

- (1) How to prescribe PBS-subsidised omalizumab therapy.

(a) Initial treatment:

Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy.

All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab.

(b) Continuing treatment:

Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response.

- (2) Baseline measurements to determine response:

Services Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Services Australia will assess response according to these revised baseline measurements.

- (3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:



A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.

(4) Monitoring of patients:

Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.

**Note** The Services Australia website ([www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.

**Note** For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or [medinfo.phauno@novartis.com](mailto:medinfo.phauno@novartis.com)

**Note** Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at [www.nationalasthma.org.au](http://www.nationalasthma.org.au)); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

#### **Authority required**

Uncontrolled severe allergic asthma

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either: a (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV<sub>1</sub>) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability, **AND**
- Patient must have a duration of asthma of at least 1 year, **AND**
- Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE, **AND**
- Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application, **AND**
- Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records, **AND**
- Patient must not receive more than 28 weeks of treatment under this restriction.

#### **Population criteria:**

- Patient must be aged 6 to less than 12 years.

#### **Treatment criteria:**

- Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.

#### **Clinical criteria:**

- Patient must be under the care of the same physician for at least 6 months.

Optimised asthma therapy includes:

(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative; **AND**

(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.

If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.

The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application:

- (a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), **AND**

(b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed.

This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with omalizumab.

A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.

The authority application must be made in writing and must include:

- (1) a completed authority prescription form; and
- (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

The following must be provided at the time of application and documented in the patient's medical records:

- (a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and
- (b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and
- (c) the IgE result and date; and
- (d) Asthma Control Questionnaire (ACQ-5) score; or
- (e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.

### omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe

10967F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	107.60	Xolair [NV]

### omalizumab 150 mg/mL injection, 1 mL syringe

10973M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	6	..	215.19	Xolair [NV]

## COUGH AND COLD PREPARATIONS

### EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS

#### *Mucolytics*

#### ▪ DORNASE ALFA

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

#### **Authority required (STREAMLINED)**

##### **5740**

Cystic fibrosis

#### **Population criteria:**

- Patient must be 5 years of age or older.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with dornase alfa at a dose of 2.5 mg daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

#### **Authority required (STREAMLINED)**

##### **5634**

Cystic fibrosis

#### **Clinical criteria:**

- Patient must have a severe clinical course with frequent respiratory exacerbations or chronic respiratory symptoms (including chronic or recurrent cough, wheeze or tachypnoea) requiring hospital admissions more frequently than 3 times per year; OR
- Patient must have significant bronchiectasis on chest high resolution computed tomography scan; OR

- Patient must have severe cystic fibrosis bronchiolitis with persistent wheeze non-responsive to conventional medicines; OR
- Patient must have severe physiological deficit measure by forced oscillation technique or multiple breath nitrogen washout and failure to respond to conventional therapy.

**Population criteria:**

- Patient must be less than 5 years of age.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Following an initial 6 months therapy, a comprehensive assessment must be undertaken and documented. Treatment with this drug should cease if there is not agreement of benefit, as there is always the possibility of harm from unnecessary use. Further reassessments must be undertaken and documented at six-monthly intervals.

**Authority required (STREAMLINED)****5635**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have initiated treatment with dornase alfa at an age of less than 5 years, **AND**
- Patient must have undergone a comprehensive assessment which documents agreement that dornase alfa treatment is continuing to produce worthwhile benefit.

**Population criteria:**

- Patient must be 5 years of age or older.

Further reassessments must be undertaken and documented at six-monthly intervals. Treatment with this drug should cease if there is not agreement of benefit as there is always the possibility of harm from unnecessary use.

**dornase alfa 2.5 mg/2.5 mL inhalation solution, 30 x 2.5 mL ampoules**

5704F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*1490.98	Pulmozyme [RO]

**■ MANNITOL**

**Note** It is highly desirable that all patients be included in the national cystic fibrosis patient database.

**Authority required (STREAMLINED)****7362**

Cystic fibrosis

**Clinical criteria:**

- The treatment must be as monotherapy, **AND**
- Patient must be intolerant or inadequately responsive to dornase alfa.

**Population criteria:**

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; **AND**
- (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

**Authority required (STREAMLINED)****7367**

Cystic fibrosis

**Clinical criteria:**

- The treatment must be in combination with dornase alfa, **AND**
- Patient must be inadequately responsive to dornase alfa, **AND**
- Patient must have trialled hypertonic saline for this condition.

**Population criteria:**

- Patient must be 6 years of age or older.

Patient must have been assessed for bronchial hyperresponsiveness as per the TGA approved Product Information initiation dose assessment for this drug, prior to therapy with this drug, with a negative result.

Patient must be assessed at a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis or by a specialist physician or paediatrician in consultation with such a unit.

## RESPIRATORY SYSTEM

Prior to therapy with this drug, a baseline measurement of forced expiratory volume in 1 second (FEV1) must be undertaken during a stable period of the disease.

Initial therapy is limited to 3 months treatment with mannitol at a dose of 400 mg twice daily.

To be eligible for continued PBS-subsidised treatment with this drug following 3 months of initial treatment:

- (1) the patient must demonstrate no deterioration in FEV1 compared to baseline; AND
- (2) the patient or the patient's family (in the case of paediatric patients) and the treating physician(s) must report a benefit in the clinical status of the patient.

Further reassessments must be undertaken and documented at six-monthly intervals. Therapy with this drug should cease if there is not general agreement of benefit as there is always the possibility of harm from unnecessary use.

### mannitol 40 mg powder for inhalation, 280 capsules

2015C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	4	5	..	*1789.20	Bronchitol [HT]

## OTHER RESPIRATORY SYSTEM PRODUCTS

### OTHER RESPIRATORY SYSTEM PRODUCTS

*Other respiratory system products*

#### ■ ELEXACAFTOR + TEZACAFTOR + IVACAFTOR (&) IVACAFTOR

**Note** For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elexacaftor/ tezacaftor/ ivacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

#### Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

#### **Population criteria:**

- Patient must be at least 6 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

#### Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be at least 6 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg tablet [56] (&) ivacaftor 150 mg tablet [28], 84**

12936W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Trikafta [VR]

**▪ ELEXACAFITOR + TEZACAFITOR + IVACAFTOR (&) IVACAFTOR**

**Note** For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elexacaftor/ tezacaftor/ ivacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

**Population criteria:**

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged between 6 and 11 years inclusive.  
This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

## elexacaftor 50 mg + tezacaftor 25 mg + ivacaftor 37.5 mg tablet [56] (&) ivacaftor 75 mg tablet [28], 84

13276R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Trikafta [VR]

### ▪ ELEXACAFITOR + TEZACAFITOR + IVACAFITOR (&) IVACAFITOR

**Note** For the purposes of this restriction, PBS-subsidised 'CFTR modulator' means ivacaftor, lumacaftor/ivacaftor, tezacaftor/ivacaftor and elexacaftor/ tezacaftor/ ivacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

#### Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must have at least one F508del mutation in the cystic fibrosis transmembrane conductance (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, prior to initiating treatment with this drug.

#### **Population criteria:**

- Patient must be 2 to 5 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient having at least one F508del mutation - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

#### Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

#### **Population criteria:**

- Patient must be 2 to 5 years of age.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) details of the proposed prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**elexacaftor 100 mg + tezacaftor 50 mg + ivacaftor 75 mg granules [28] (& ivacaftor 75 mg granules [28], 56**

14228W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Trikafta [VR]

**elexacaftor 80 mg + tezacaftor 40 mg + ivacaftor 60 mg granules [28] (& ivacaftor 59.5 mg granules [28], 56**

14227T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Trikafta [VR]

## ■ IVACAFTOR

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

### Authority required

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (non-gating mutations)

### **Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have at least one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or in vitro assay data, **AND**
- Patient must not have either: (i) G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; (ii) other gating (class III) mutation in the CFTR gene, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

### **Population criteria:**

- Patient must be aged 4 months or older.

For the purposes of this restriction, the list of mutations considered to be responsive to ivacaftor is defined in the TGA approved Product Information.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the specific mutation considered to be responsive to ivacaftor as listed in the TGA approved Product Information. Quote each of the: (i) the specific mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

### Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment (non-gating mutations)

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**ivacaftor 150 mg tablet, 56**

14153X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Kalydeco [VR]

**ivacaftor 50 mg granules, 56 sachets**

14148P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Kalydeco [VR]

**ivacaftor 75 mg granules, 56 sachets**

14167P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Kalydeco [VR]

**ivacaftor 25 mg granules, 56 sachets**

14155B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Kalydeco [VR]

■ **IVACAFTOR**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment - New patient (gating mutations)

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**



- Patient must have G551D mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene on at least 1 allele; OR
- Patient must have other gating (class III) mutation in the CFTR gene on at least 1 allele, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating G551D mutation or other gating (Class III) mutation on the CFTR gene - quote each of the: (i) the specific CFTR mutation listed in the TGA approved Product Information, (ii) name of the pathology report provider, (iii) date of pathology report, (iv) unique identifying number/code that links the pathology result to the individual patient, and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Note** For the purposes of this restriction, the list of gating mutations are: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment (gating mutations)

**Clinical criteria:**

- Patient must be assessed through a cystic fibrosis clinic/centre which is under the control of specialist respiratory physicians with experience and expertise in the management of cystic fibrosis. If attendance at such a unit is not possible because of geographical isolation, management (including prescribing) may be in consultation with such a unit, **AND**
- Patient must have received PBS-subsidised initial therapy with ivacaftor, given concomitantly with standard therapy, for this condition, **AND**
- Patient must not receive more than 24 weeks of treatment under this restriction per authority application, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged 4 months or older.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet twice a week, if the patient is concomitantly receiving one of the following strong CYP3A4 drugs inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole. Where a patient is concomitantly receiving a strong CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 28 weeks.

Dosage of ivacaftor must not exceed the dose of one tablet (150 mg) or one sachet once daily, if the patient is concomitantly receiving one of the following moderate CYP3A4 inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil. Where a patient is concomitantly receiving a moderate CYP3A4 inhibitor, a single supply of 56 tablets or sachets of ivacaftor will last for 8 weeks.

Ivacaftor is not PBS-subsidised for this condition as a sole therapy.

Ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**ivacaftor 150 mg tablet, 56**

10170G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Kalydeco [VR]

## RESPIRATORY SYSTEM

### ivacaftor 50 mg granules, 56 sachets

11105L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Kalydeco [VR]

### ivacaftor 75 mg granules, 56 sachets

11098D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Kalydeco [VR]

### ivacaftor 25 mg granules, 56 sachets

14156C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	20306.25	Kalydeco [VR]

## ▪ LUMACAFTOR + IVACAFTOR

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

#### **Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

#### **Population criteria:**

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

#### **Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**

- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be aged between 6 and 11 years inclusive.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**lumacaftor 100 mg + ivacaftor 125 mg tablet, 112**

11465K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	16921.88	Orkambi [VR]

**▪ LUMACAFITOR + IVACAFITOR**

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

**Population criteria:**

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Authority required**

Cystic fibrosis

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**

## RESPIRATORY SYSTEM

- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

### Population criteria:

- Patient must be 12 years of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- a completed authority prescription; and
- a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

### lumacaftor 200 mg + ivacaftor 125 mg tablet, 112

11466L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	16921.88	Orkambi [VR]

## ▪ LUMACFTOR + IVACFTOR

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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

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

**Note** Special Pricing Arrangements apply.

### Authority required

Cystic fibrosis

Treatment Phase: Initial treatment

### Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

### Clinical criteria:

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition.

### Population criteria:

- Patient must be 1 year of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- a completed authority prescription; and
- a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

### Authority required

Cystic fibrosis

Treatment Phase: Continuing treatment

### Treatment criteria:

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**

- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 1 year of age or older.

This pharmaceutical benefit is not PBS-subsidised for this condition in a patient who is currently receiving one of the strong CYP3A4 inducers outlined in the Product Information.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**lumacaftor 100 mg + ivacaftor 125 mg granules, 56 sachets**

11866M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	16921.88	Orkambi [VR]

**lumacaftor 150 mg + ivacaftor 188 mg granules, 56 sachets**

11851R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	16921.88	Orkambi [VR]

**lumacaftor 75 mg + ivacaftor 94 mg granules, 56 sachets**

13798F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	±1	5	..	16921.88	Orkambi [VR]

**▪ TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**

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

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

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

**Population criteria:**

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient being homozygous for the F508del mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient; and
- (4) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Authority required**

Cystic fibrosis - homozygous for the F508del mutation

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56**

11854X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	18952.50	Symdeko [VR]

▪ **TEZACAFTOR + IVACAFTOR (&) IVACAFTOR**

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

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

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** For the purposes of this restriction, CFTR modulators, regardless if they are available as a single drug or in combination, are currently: elexacaftor, ivacaftor, lumacaftor, tezacaftor.

**Note** Special Pricing Arrangements apply.

**Authority required**

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**

- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have at least one residual function (RF) mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor with ivacaftor, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition, **AND**
- Patient must have either chronic sinopulmonary disease or gastrointestinal and nutritional abnormalities.

**Population criteria:**

- Patient must be 12 years of age or older.

For the purposes of this restriction, the list of mutations considered to be responsive to tezacaftor with ivacaftor is defined in the TGA approved product information.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Authority Application Supporting Information Form; and
- (3) details of the pathology report substantiating the patient having at least one RF mutation on the CFTR gene - quote each of the: (i) name of the pathology report provider, (ii) date of pathology report, (iii) unique identifying number/code that links the pathology result to the individual patient ; and
- (4) CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**Authority required**

Cystic fibrosis - one residual function (RF) mutation

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a specialist respiratory physician with expertise in cystic fibrosis or in consultation with a specialist respiratory physician with expertise in cystic fibrosis if attendance is not possible due to geographic isolation, **AND**
- Must be treated in a centre with expertise in cystic fibrosis or in consultation with a centre with expertise in cystic fibrosis if attendance is not possible due to geographic isolation.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapy for this condition, **AND**
- The treatment must be given concomitantly with standard therapy for this condition.

**Population criteria:**

- Patient must be 12 years of age or older.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg and ivacaftor 150 mg tablets on alternate days if the patient is concomitantly receiving one of the following moderate CYP3A4 drugs inhibitors: amprenavir, aprepitant, atazanavir, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil.

Dosage of tezacaftor with ivacaftor is tezacaftor 100 mg/ivacaftor 150 mg twice weekly (approximately 3 or 4 days apart) if the patient is concomitantly receiving one of the following strong CYP3A4 inhibitors: boceprevir, clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telaprevir, telithromycin, voriconazole.

Tezacaftor with ivacaftor is not PBS-subsidised for this condition in a patient who is currently receiving one of the following CYP3A4 inducers:

Strong CYP3A4 inducers: avasimibe, carbamazepine, phenobarbital, phenytoin, rifabutin, rifampicin, St. John's wort;

Moderate CYP3A4 inducers: bosentan, efavirenz, etravirine, modafinil, nafcillin;

Weak CYP3A4 inducers: armodafinil, echinacea, pioglitazone, rufinamide.

The authority application must be in writing and must include:

- (1) a completed authority prescription; and
- (2) a completed Cystic Fibrosis Continuing Authority Application Supporting Information Form; and
- (3) current CYP3A4 inhibitors, CYP3A4 inducers and IV antibiotics.

**tezacaftor 100 mg + ivacaftor 150 mg tablet [28] (&) ivacaftor 150 mg tablet [28], 56**

11863J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	18952.50	Symdeko [VR]

VARIOUS  
ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

*Iron chelating agents*

DEFERASIROX

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

**deferasirox 180 mg tablet, 30**

11556F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*174.12	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 360 mg tablet, 30**

11533B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*348.24	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 90 mg tablet, 30**

11499F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*87.06	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

DEFERASIROX

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

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis.

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia.

**deferasirox 125 mg dispersible tablet, 28**

11247Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*593.70	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 250 mg dispersible tablet, 28**

11240N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*818.70	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 500 mg dispersible tablet, 28**

11234G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	5	..	*2374.68	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

HSD (Public)



## ▪ DEFERASIROX

**Note** A patient's median life expectancy is determined by the severity of their underlying disease.

**Note** Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

**Note** Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

### Authority required

Chronic iron overload

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

### deferasirox 180 mg tablet, 30

11500G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*174.12	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

### deferasirox 360 mg tablet, 30

11536E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*348.24	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

### deferasirox 90 mg tablet, 30

11519G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*87.06	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

## ▪ DEFERASIROX

### Authority required (STREAMLINED)

#### **8328**

Chronic iron overload

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must be transfusion dependent, **AND**
- Patient must not have a malignant disorder of erythropoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

### Authority required (STREAMLINED)

#### **8329**

Chronic iron overload

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must not be transfusion dependent, **AND**
- The condition must be thalassaemia, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

### Authority required (STREAMLINED)

#### **8326**

Chronic iron overload

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have previously received PBS-subsidised therapy with deferasirox for this condition.

**Note** Interruption of treatment should be considered if serum ferritin levels fall consistently below 500 microgram/mL.

### deferasirox 125 mg dispersible tablet, 28

5654N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*593.70	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 250 mg dispersible tablet, 28**

5655P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*818.70	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 500 mg dispersible tablet, 28**

5656Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*2374.68	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 180 mg tablet, 30**

11535D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*174.12	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 360 mg tablet, 30**

11555E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*348.24	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

**deferasirox 90 mg tablet, 30**

11534C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*87.06	<sup>a</sup> Deferasirox ARX [XT] <sup>a</sup> DEFERASIROX-TEVA [TB] <sup>a</sup> Jadenu [NM]	<sup>a</sup> Deferasirox Sandoz [SZ] <sup>a</sup> Eferas [AF] <sup>a</sup> Pharmacor Deferasirox FC [CR]

▪ **DEFERASIROX**

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

**Note** A patient's median life expectancy is determined by the severity of their underlying disease.

**Note** Patients with underlying myelodysplastic syndrome are considered to have a median life expectancy exceeding five years if they are classified as:

- low risk according to the International Prognostic Scoring System (IPSS); or
- very low and low risk according to the Revised International Prognostic Scoring System (IPSS-R); or
- very low and low risk according to the WHO classification based Prognostic Scoring System (WPSS).

**Note** Patients with underlying myelofibrosis have a median life expectancy exceeding five years if they are classified as:

- low or intermediate risk according to the International Prognostic Scoring System (IPSS); or
- low or intermediate-1 risk according to Dynamic International Prognostic Scoring System (DIPSS).

**Authority required**

Chronic iron overload

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be red blood cell transfusion dependent, **AND**
- Patient must have a serum ferritin level of greater than 1000 microgram/L, **AND**
- Patient must have a malignant disorder of haemopoiesis, **AND**
- Patient must have a median life expectancy exceeding five years.

**deferasirox 125 mg dispersible tablet, 28**

11235H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*593.70	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 250 mg dispersible tablet, 28**

11239M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*818.70	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

**deferasirox 500 mg dispersible tablet, 28**

11231D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	6	2	..	*2374.68	<sup>a</sup> Deferasirox Juno [JU]	<sup>a</sup> Pharmacor Deferasirox [CR]

▪ **DEFERIPRONE**

**Authority required (STREAMLINED)**

**6448**

Iron overload

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be unable to take desferrioxamine therapy.

**Authority required (STREAMLINED)**

**6403**

Iron overload

HSD (Public)

**Clinical criteria:**

- Patient must have thalassaemia major, **AND**
- Patient must be one in whom desferrioxamine therapy has proven ineffective.

**deferiprone 1 g tablet, 50**

11747G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	6	5	..	*2311.38	Feriprox [EU]

**deferiprone 100 mg/mL oral liquid, 250 mL**

5658T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	5	5	..	*963.10	Feriprox [EU]

**deferiprone 500 mg tablet, 100**

5657R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	3	5	..	*1155.69	Feriprox [EU]

**■ DESFERRIOXAMINE****Authority required (STREAMLINED)****6394**

Disorders of erythropoiesis

**Clinical criteria:**

- The condition must be associated with treatment-related chronic iron overload.

**desferrioxamine mesilate 2 g injection, 1 vial**

5661Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	60	5	..	*2614.80	DBL Desferrioxamine Mesilate [PF]

**desferrioxamine mesilate 500 mg injection, 10 vials**

5662B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	40	5	..	*5555.20	DBL Desferrioxamine Mesilate [PF]

*Drugs for treatment of hyperkalemia and hyperphosphatemia***■ LANTHANUM****Authority required (STREAMLINED)****5530**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**lanthanum 500 mg chewable tablet, 2 x 45**

5780F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*330.80	Fosrenol [TK]

**lanthanum 750 mg chewable tablet, 6 x 15**

5781G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*499.52	Fosrenol [TK]

**lanthanum 1 g chewable tablet, 6 x 15**

5782H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*562.34	Fosrenol [TK]

**■ SEVELAMER**

**Note** Pharmaceutical benefits that have the forms sevelamer hydrochloride 800 mg and sevelamer carbonate 800 mg tablet are equivalent for the purposes of substitution

**Authority required (STREAMLINED)****5530**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**

- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sevelamer carbonate 800 mg tablet, 180**

11855Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*317.62	<sup>a</sup> ARX-SEVELAMER [XT] <sup>a</sup> Sevelamer Lupin [GQ]	<sup>a</sup> Sevelamer Apotex [TX]

**sevelamer hydrochloride 800 mg tablet, 180**

9546K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*317.62	<sup>a</sup> Renagel [GZ]

**▪ SUCROFERRIC OXYHYDROXIDE****Authority required (STREAMLINED)****5530**

Hyperphosphataemia

Treatment Phase: Initiation and stabilisation

**Clinical criteria:**

- The condition must not be adequately controlled by calcium, **AND**
- Patient must have a serum phosphate of greater than 1.6 mmol per L at the commencement of therapy; OR
- The condition must be where a serum calcium times phosphate product is greater than 4 at the commencement of therapy, **AND**
- The treatment must not be used in combination with any other non-calcium phosphate binding agents.

**Treatment criteria:**

- Patient must be undergoing dialysis for chronic kidney disease.

**sucroferric oxyhydroxide 2.5 g (iron 500 mg) chewable tablet, 90**

10233N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	2	5	..	*680.00	Velphoro [VL]

*Other therapeutic products***▪ DIFELIKEFALIN****Note** See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):

Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. J Patient Rep Outcomes. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z

The WI-NRS scale is available as downloadable document in the supplementary information section at:

[www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/)**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).**Note** No increase in the maximum number of repeats may be authorised.**Note** Special Pricing Arrangements apply.**Authority required**

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be on optimised haemodialysis, **AND**
- Patient must be on haemodialysis for at least 3 months, **AND**
- The condition must be confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus, **AND**
- Patient must have experienced itch that persists for at least 6 weeks despite best supportive care, **AND**
- Patient must have a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) baseline score of more than 4, **AND**
- Patient must not receive more than 12 weeks of treatment under this restriction.

**Treatment criteria:**

- Must be treated by a nephrologist.

**Population criteria:**

- Patient must be at least 18 years of age.

Prescriber must exclude any other causes of pruritus which include any of the following:

- drug/dialysis related (e.g., opioid-related pruritus);
- drug hypersensitivity or adverse effect; contact dermatitis; allergy;
- differential diagnoses (e.g., xerosis; infestations; iron deficiency; liver disease; polycythaemia vera/leukemia/lymphoma; hypothyroidism; uncontrolled diabetes).

Best supportive care for patients with chronic kidney disease-associated pruritus is not limited to but includes:

- (i) optimisation of dialysis;
- (ii) skin hydration and nutrition (with the use of moisturiser, emollients, barrier creams or oils);
- (iii) patient education on the importance of avoiding or minimising scratching.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 2 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

### difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14140F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	2	..	540.00	Korsuva [CS]

## ▪ DIFELIKEFALIN

**Note** See the following article for details on the 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS):

Vernon MK, Swett LL, Speck RM, et al. Psychometric validation and meaningful change thresholds of the Worst Itching Intensity Numerical Rating Scale for assessing itch in patients with chronic kidney disease-associated pruritus. *J Patient Rep Outcomes*. 2021;5(1):134. Published 2021 Dec 24. doi:10.1186/s41687-021-00404-z

The WI-NRS scale is available as downloadable document in the supplementary information section at: [www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC8709801/)

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

**Note** Special Pricing Arrangements apply.

#### Authority required

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have demonstrated an adequate response to treatment with this drug including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

#### **Treatment criteria:**

- Must be treated by a nephrologist; OR
- Must be treated by a medical practitioner in consultation with a nephrologist.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

#### Authority required

Moderate to severe pruritus (itching) associated with chronic kidney disease

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

#### **Clinical criteria:**

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024, **AND**
- Patient must have met all other PBS eligibility criteria that a non-'Grandfather' patient would ordinarily be required to meet, meaning that at the time non-PBS-subsidised supply was commenced, the patient: (i) was on optimised haemodialysis; (ii) was on haemodialysis for at least 3 months; (iii) had a condition confirmed based on both physical examination and patient history to exclude any factors that may be triggering the pruritus; (iv) had experienced itch that persists for at least 6 weeks despite best supportive care; (v) had a 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) of more than 4 at baseline, **AND**
- Patient must have demonstrated an adequate response to the most recent non-PBS-subsidised treatment with this drug for this condition, including at least a 3-point improvement from baseline in 24-hour Worst Itching Intensity Numerical Rating Scale (WI-NRS) score.

#### **Treatment criteria:**

- Must be treated by a nephrologist.

#### **Population criteria:**

- Patient must be at least 18 years of age.

Confirmation of eligibility for treatment with diagnostic reports must be documented in the patient's medical records.

At the time of authority application, medical practitioners must request the appropriate number of vials to provide sufficient drug, based on the dry body weight of the patient (in kg), adequate for 4 weeks, according to the specified dosage in the approved Product Information (PI). Up to a maximum of 5 repeats will be authorised. No more than 4 doses per week will be authorised even if the number of haemodialysis treatments in a week exceeds 4.

**Note** A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the continuing treatment criteria.

**Note** This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

## VARIOUS

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### difelikefalin 50 microgram/mL injection, 12 x 1 mL vials

14141G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	Brand Name and Manufacturer
	1	5	..	540.00	Korsuva [CS]

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# Highly Specialised Drugs Program (Community Access)

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## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

#### HYPOTHALAMIC HORMONES

##### *Somatostatin and analogues*

#### LANREOTIDE

**Note** Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

##### **Authority required (STREAMLINED)**

**16024**

Acromegaly

Treatment Phase: Initial treatment

##### **Treatment criteria:**

- Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting.

##### **Clinical criteria:**

- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

##### **Authority required (STREAMLINED)**

**16055**

Acromegaly

Treatment Phase: Continuing treatment

##### **Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be active, **AND**
- Patient must have persistent elevation of mean growth hormone levels of greater than 2.5 micrograms per litre, **AND**
- The treatment must be after failure of other therapy including dopamine agonists; OR
- The treatment must be as interim treatment while awaiting the effects of radiotherapy and where treatment with dopamine agonists has failed; OR
- The treatment must be in a patient who is unfit for or unwilling to undergo surgery and where radiotherapy is contraindicated, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after lanreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised pegvisomant.

In a patient treated with radiotherapy, lanreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission.

##### **Authority required (STREAMLINED)**

**16057**

Functional carcinoid tumour

Treatment Phase: Initial treatment

##### **Treatment criteria:**

- Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting.

##### **Clinical criteria:**

- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.



Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**Authority required (STREAMLINED)**

**15955**

Functional carcinoid tumour

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be causing intractable symptoms, **AND**
- Patient must have experienced on average over 1 week, 3 or more episodes per day of diarrhoea and/or flushing, which persisted despite the use of anti-histamines, anti-serotonin agents and anti-diarrhoea agents, **AND**
- Patient must be one in whom surgery or antineoplastic therapy has failed or is inappropriate, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months' therapy at a dose of 120 mg every 28 days.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

**lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe**

11289E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2630.19	31.60	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

**lanreotide 60 mg/0.5 mL injection, 0.5 mL syringe**

11315M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1748.13	31.60	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

**lanreotide 90 mg/0.5 mL injection, 0.5 mL syringe**

11316N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2310.41	31.60	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

■ **LANREOTIDE**

**Note** Somatuline Autogel and Mytolac products are equivalent for the purpose of substitution. Pharmacists should ensure that patients are educated regarding the product differences upon dispensing.

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

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

**Authority required (STREAMLINED)**

**16056**

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist practicing in a hospital who is either: (i) an endocrinologist, (ii) an oncologist; OR
- Must be treated by a medical practitioner working under the direct supervision of one of the above mentioned specialist types within a hospital setting.

**Clinical criteria:**

- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.
- WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

**Authority required (STREAMLINED)**

**16133**

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Population criteria:**

- Patient must be at least 18 years of age.
- WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

# SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## lanreotide 120 mg/0.5 mL injection, 0.5 mL syringe

11736Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*2630.19	31.60	<sup>a</sup> Mytolac [GH]	<sup>a</sup> Somatuline Autogel [IS]

## ■ OCTREOTIDE

### Authority required (STREAMLINED)

**8197**

Acromegaly

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be controlled with octreotide immediate release injections, **AND**
- The treatment must cease in a patient treated with radiotherapy if there is biochemical evidence of remission (normal IGF1) after octreotide has been withdrawn for at least 4 weeks (8 weeks after the last dose), **AND**
- The treatment must cease if IGF1 is not lower after 3 months of treatment, **AND**
- The treatment must not be given concomitantly with PBS-subsidised lanreotide or pegvisomant for this condition.

In a patient treated with radiotherapy, octreotide should be withdrawn every 2 years in the 10 years after radiotherapy for assessment of remission

### Authority required (STREAMLINED)

**8208**

Functional carcinoid tumour

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

### Authority required (STREAMLINED)

**8198**

Vasoactive intestinal peptide secreting tumour (VIPoma)

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved symptom control on octreotide immediate release injections, **AND**
- The treatment must cease if there is failure to produce a clinically significant reduction in the frequency and severity of symptoms after 3 months therapy at a dose of 30 mg every 28 days and having allowed adequate rescue therapy with octreotide immediate release injections.

Dosage and tolerance to the drug should be assessed regularly and the dosage should be titrated slowly downwards to determine the minimum effective dose.

## octreotide 10 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

11501H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*829.39	31.60	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

## octreotide 20 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

11537F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1099.29	31.60	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

## octreotide 30 mg modified release injection [1 vial] (& inert substance diluent [2 mL syringe], 1 pack

11512X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1255.99	31.60	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

## ■ OCTREOTIDE

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

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

### Authority required (STREAMLINED)

**10075**

Non-functional gastroenteropancreatic neuroendocrine tumour (GEP-NET)

#### Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must be unresectable locally advanced disease or metastatic disease, **AND**
- The condition must be World Health Organisation (WHO) grade 1 or 2, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

#### Population criteria:

- Patient must be aged 18 years or older.
- WHO grade 1 of GEP-NET is defined as a mitotic count (10HPF) of less than 2 and Ki-67 index (%) of less than or equal to 2.

WHO grade 2 of GEP-NET is defined as a mitotic count (10HPF) of 2-20 and Ki-67 index (%) of 3-20.

**octreotide 30 mg modified release injection [1 vial] (&) inert substance diluent [2 mL syringe], 1 pack**

11896D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*1255.99	31.60	<sup>a</sup> Octreotide Depot [TB]	<sup>a</sup> Sandostatin LAR [NV]

■ **ANTIINFECTIVES FOR SYSTEMIC USE**

■ **ANTIVIRALS FOR SYSTEMIC USE**

**DIRECT ACTING ANTIVIRALS**

■ **CABOTEGRAVIR (&) RILPIVIRINE**

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

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

**Note** Special Pricing Arrangements apply.

**Note** It is recommended that patients have previously received 4 weeks of PBS-subsidised initial oral lead-in treatment with cabotegravir and rilpivirine.

**Authority required (STREAMLINED)**

**12636**

HIV infection

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**cabotegravir 600 mg/3 mL modified release injection [3 mL vial] (&) rilpivirine 900 mg/3 mL modified release injection [3 mL vial], 1 pack**

12937X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	5	..	2828.67	31.60	Cabenuva [VI]	

NP

*Nucleosides and nucleotides excl. reverse transcriptase inhibitors*

■ **GANCICLOVIR**

**Authority required (STREAMLINED)**

**5000**

Cytomegalovirus retinitis

**Clinical criteria:**

- Patient must be severely immunocompromised, including due to HIV infection.

**ganciclovir 500 mg injection, 5 vials**

10228N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	1	..	*250.13	31.60	<sup>a</sup> Cymevene [PB]	<sup>a</sup> GANCICLOVIR SXP [XC]

NP

■ **VALGANCICLOVIR**

**Authority required (STREAMLINED)**

**4980**

Cytomegalovirus retinitis

**Clinical criteria:**

- Patient must have HIV infection.

**valganciclovir 50 mg/mL powder for oral liquid, 100 mL**

10277X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	11	5	..	*#4397.97	31.60	Valcyte [PB]	

NP

**valganciclovir 450 mg tablet, 60**

10306K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*503.93	31.60	<sup>a</sup> Valganciclovir Sandoz [SZ]	<sup>a</sup> Valganciclovir Viatrix [AL]

NP

*Protease inhibitors*

■ **ATAZANAVIR**

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

## ANTIINFECTIVES FOR SYSTEMIC USE

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**atazanavir 200 mg capsule, 60**

10349Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*841.89	31.60	Reyataz [BQ]

### ■ ATAZANAVIR

**Note** Pharmaceutical benefits that have the form atazanavir 300 mg capsule, 30 and pharmaceutical benefits that have the form atazanavir 300 mg capsule, 60 are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**atazanavir 300 mg capsule, 30**

10321F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*633.57	31.60	Reyataz [BQ]

### ■ ATAZANAVIR + COBICISTAT

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**atazanavir 300 mg + cobicistat 150 mg tablet, 30**

10692R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*714.47	31.60	Evotaz [BQ]

### ■ DARUNAVIR

**Note** Pharmaceutical benefits that have the forms darunavir tablet 600 mg, 2 x 30 and darunavir tablet 600 mg (as ethanolate), 60 are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)**

**5094**

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir twice daily, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

HSD  
(Community)

**darunavir 600 mg tablet, 2 x 30**

12946J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*1373.73	31.60	<sup>a</sup> Darunavir Juno [JU]

**darunavir 600 mg tablet, 60**

10329P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*1373.73	31.60	<sup>a</sup> Prezista [JC]

**▪ DARUNAVIR**

**Note** Pharmaceutical benefits that have the form darunavir tablet 800 mg and pharmaceutical benefits that have the form darunavir tablet 800 mg (as ethanolate) are equivalent for the purposes of substitution.

**Authority required (STREAMLINED)****4313**

Human immunodeficiency virus (HIV) infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must be co-administered with 100 mg ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**
- Patient must not have demonstrated darunavir resistance associated mutations detected on resistance testing. Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**darunavir 800 mg tablet, 30**

10367P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*927.37	31.60	<sup>a</sup> Prezista [JC]

**darunavir 800 mg tablet, 30**

12111K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*927.37	31.60	<sup>a</sup> Darunavir Juno [JU]

**▪ RITONAVIR****Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**ritonavir 100 mg tablet, 30**

10273Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	24	5	..	*654.27	31.60	Norvir [VE]

***Nucleoside and nucleotide reverse transcriptase inhibitors*****▪ ABACAVIR****Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

## ANTIINFECTIVES FOR SYSTEMIC USE

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### abacavir 300 mg tablet, 60

10294T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*379.25	31.60	Ziagen [VI]

### ▪ ABACAVIR

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

#### Authority required

Human immunodeficiency virus (HIV) infection

#### Population criteria:

- Patient must be less than 13.00 years of age.

#### Clinical criteria:

- Patient must be unable to take a solid dose form of this drug, **AND**
- The treatment must be in combination with other antiretroviral agents.

### abacavir 20 mg/mL oral liquid, 240 mL

10356C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	8	5	..	*563.79	31.60	Ziagen [VI]

### ▪ ADEFOVIR

**Note** Pharmaceutical benefits that have the brand Adefovir Dipivoxil Tablets 10 mg (SigmaPharm Laboratories) may be substituted for pharmaceutical benefits that have the brand APO-Adefovir, in case of shortage.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

#### Authority required (STREAMLINED)

**4490**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

#### Authority required (STREAMLINED)

**4510**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

### adefovir dipivoxil 10 mg tablet, 30

13777D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*1029.65	31.60	Adefovir Dipivoxil Tablets 10 mg (SigmaPharm Laboratories) [XW]

### ▪ ENTECAVIR

#### Authority required (STREAMLINED)

**4993**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

#### Authority required (STREAMLINED)

**5036**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**entecavir 500 microgram tablet, 30**

10279B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*80.95	31.60	<sup>a</sup> ENTAC [LR] <sup>a</sup> Entecavir GH [GQ] <sup>a</sup> Entecavir Sandoz [SZ] <sup>a</sup> ENTECAVIR-WGR [WG]	<sup>a</sup> ENTECAVIR APO [GX] <sup>a</sup> ENTECAVIR RBX [RA] <sup>a</sup> Entecavir Viatris [AL]

**■ ENTECAVIR**

**Note** PBS-subsidised entecavir monohydrate must be used as monotherapy.

**Authority required (STREAMLINED)****5044**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have failed lamivudine, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Authority required (STREAMLINED)****5037**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
  - Patient must have failed lamivudine, **AND**
  - Patient must have detectable HBV DNA.
- Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**entecavir 1 mg tablet, 30**

10353X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*124.15	31.60	<sup>a</sup> ENTECAVIR APO [GX] <sup>a</sup> Entecavir Sandoz [SZ] <sup>a</sup> ENTECAVIR-WGR [WG]	<sup>a</sup> ENTECAVIR RBX [RA] <sup>a</sup> Entecavir Viatris [AL]

**■ LAMIVUDINE****Authority required (STREAMLINED)****4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**lamivudine 10 mg/mL oral liquid, 240 mL**

10320E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	8	5	..	*474.43	31.60	3TC [VI]

**lamivudine 150 mg tablet, 60**

10348P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*101.19	31.60	<sup>a</sup> 3TC [VI] <sup>a</sup> Lamivudine Viatris [AL]	<sup>a</sup> Lamivudine Alphapharm [AF]

# ANTIINFECTIVES FOR SYSTEMIC USE

## lamivudine 300 mg tablet, 30

10311Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*101.19	31.60	<sup>a</sup> 3TC [VI]	<sup>a</sup> Lamivudine Alphapharm [AF]

### ■ LAMIVUDINE

#### Authority required (STREAMLINED)

**4993**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must not have cirrhosis, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by confirmed elevated serum ALT or liver biopsy.

#### Authority required (STREAMLINED)

**5036**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must have cirrhosis, **AND**
  - Patient must have detectable HBV DNA.
- Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

## lamivudine 100 mg tablet, 28

10315X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*59.55	31.60	<sup>a</sup> Zetlam [AF]	
			<sup>B</sup> 2.36	*61.91	31.60	<sup>a</sup> Zeffix [RW]	

### ■ TENOFOVIR DISOPROXIL

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

**Note** Treatment is intended to prevent mother-to-child transmission of hepatitis B in the third trimester of pregnancy and to reduce the risk of viral reactivation in the mother up to 12 weeks post-partum.

#### Authority required (STREAMLINED)

**10362**

Chronic hepatitis B infection

#### Clinical criteria:

- Patient must be in the third trimester of pregnancy, **AND**
- Patient must have elevated HBV DNA levels greater than 200,000 IU/mL (1,000,000 copies/mL), in conjunction with documented hepatitis B infection.

## tenofovir disoproxil phosphate 291 mg tablet, 30

11978K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*119.71	31.60	<sup>a</sup> Tenofovir GH [GQ]	

## tenofovir disoproxil maleate 300 mg tablet, 30

11982P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*119.71	31.60	<sup>a</sup> Tenofovir Disoproxil Viatrix [AL]	

## tenofovir disoproxil fumarate 300 mg tablet, 30

11992E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	2	..	*169.79	31.60	<sup>a</sup> Tenofovir APOTEX [TX]	<sup>a</sup> TENOFOVIR ARX [XT]
						<sup>a</sup> Tenofovir Sandoz [SZ]	<sup>a</sup> Viread [GI]

### ■ TENOFOVIR DISOPROXIL

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil phosphate 291 mg tablet, tenofovir disoproxil maleate 300 mg tablet, and tenofovir disoproxil fumarate 300 mg tablet are equivalent for the purposes of substitution.

#### Authority required (STREAMLINED)

**6998**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

#### Authority required (STREAMLINED)

**6982**



HIV infection  
Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)****6980**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have detectable HBV DNA, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)****6992**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must be nucleoside analogue naive, **AND**
- Patient must have elevated HBV DNA levels greater than 20,000 IU/mL (100,000 copies/mL) if HBeAg positive, in conjunction with documented hepatitis B infection; OR
- Patient must have elevated HBV DNA levels greater than 2,000 IU/mL (10,000 copies/mL) if HBeAg negative, in conjunction with documented hepatitis B infection, **AND**
- Patient must have evidence of chronic liver injury determined by: (i) confirmed elevated serum ALT; or (ii) liver biopsy, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)****6983**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have detectable HBV DNA.

Patients with Child's class B or C cirrhosis (ascites, variceal bleeding, encephalopathy, albumin less than 30 g per L, bilirubin greater than 30 micromoles per L) should have their treatment discussed with a transplant unit prior to initiating therapy.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**Authority required (STREAMLINED)****6984**

Chronic hepatitis B infection

**Clinical criteria:**

- Patient must not have cirrhosis, **AND**
- Patient must have failed antihepadnaviral therapy, **AND**
- Patient must have repeatedly elevated serum ALT levels while on concurrent antihepadnaviral therapy of greater than or equal to 6 months duration, in conjunction with documented chronic hepatitis B infection; OR
- Patient must have repeatedly elevated HBV DNA levels one log greater than the nadir value or failure to achieve a 1 log reduction in HBV DNA within 3 months whilst on previous antihepadnaviral therapy, except in patients with evidence of poor compliance.

**Note** Patients may receive treatment in combination with lamivudine but not with other PBS-subsidised antihepadnaviral therapy.

**tenofovir disoproxil phosphate 291 mg tablet, 30**

11142K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*119.71	31.60	<sup>a</sup> Tenofovir GH [GQ]

**tenofovir disoproxil maleate 300 mg tablet, 30**

11155D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*119.71	31.60	<sup>a</sup> Tenofovir Disoproxil Viatrix [AL]

**tenofovir disoproxil fumarate 300 mg tablet, 30**

10310P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	5	..	*169.79	31.60	<sup>a</sup> Tenofovir APOTEX [TX]	<sup>a</sup> TENOFOVIR ARX [XT]

**NP** ■ **ZIDOVUDINE**

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**zidovudine 250 mg capsule, 40**

10360G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	6	5	..	*818.67	31.60	Retrovir [VI]

**zidovudine 100 mg capsule, 100**

10266H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	4	5	..	*548.67	31.60	Retrovir [VI]

**zidovudine 50 mg/5 mL oral liquid, 200 mL**

10361H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	15	5	..	*577.47	31.60	Retrovir [VI]

*Non-nucleoside reverse transcriptase inhibitors*

■ **ETRAVIRINE**

**Authority required (STREAMLINED)**

**5014**

HIV infection

**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must be antiretroviral experienced, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**etravirine 200 mg tablet, 60**

10301E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*818.89	31.60	Intence [JC]

■ **NEVIRAPINE**

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**nevirapine 10 mg/mL oral liquid, 240 mL**

10319D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	10	5	..	*1398.67	31.60	Viramune [BY]

## nevirapine 200 mg tablet, 60

10304H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*157.39	31.60	Nevirapine Viatris [AL]

## ■ RILPIVIRINE

### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

## rilpivirine 25 mg tablet, 30

10298B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*518.47	31.60	Edurant [JC]

### *Integrase inhibitors*

## ■ CABOTEGRAVIR

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

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

### Authority required (STREAMLINED)

**12619**

HIV infection

#### Clinical criteria:

- Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months, **AND**
- The treatment must be in combination with rilpivirine tablets, **AND**
- Patient must intend to proceed to treatment with intramuscular administration of cabotegravir and rilpivirine.

## cabotegravir 30 mg tablet, 30

12939B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	1	..	..	666.23	31.60	Vocabria [VI]

## ■ DOLUTEGRAVIR

### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### Authority required (STREAMLINED)

**4454**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

## dolutegravir 50 mg tablet, 30

10283F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*1249.99	31.60	Tivicay [VI]

## ■ RALTEGRAVIR

### Authority required (STREAMLINED)

**4512**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

## ANTIINFECTIVES FOR SYSTEMIC USE

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### **Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### **raltegravir 600 mg tablet, 60**

11248B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*883.35	31.60	Isentress HD [MK]

### **raltegravir 400 mg tablet, 60**

10286J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*883.35	31.60	Isentress [MK]

### *Antivirals for treatment of HIV infections, combinations*

## ▪ ABACAVIR + LAMIVUDINE

### **Authority required (STREAMLINED)**

**4527**

HIV infection

Treatment Phase: Initial

### **Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### **Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

### **Authority required (STREAMLINED)**

**4528**

HIV infection

Treatment Phase: Continuing

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### **Population criteria:**

- Patient must be aged 12 years or older, **AND**
- Patient must weigh 40 kg or more.

### **abacavir 600 mg + lamivudine 300 mg tablet, 30**

10357D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*93.27	31.60	<sup>a</sup> Abacavir/Lamivudine Viatris [AL]	<sup>a</sup> Kivexa [VI]

## ▪ BICTEGRAVIR + EMTRICITABINE + TENOFOVIR ALAFENAMIDE

### **Authority required (STREAMLINED)**

**4522**

HIV infection

Treatment Phase: Initial

### **Clinical criteria:**

- Patient must be antiretroviral treatment naive.

### **Authority required (STREAMLINED)**

**4470**

HIV infection

Treatment Phase: Continuing

### **Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

### **bictegravir 50 mg + emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30**

11649D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
<b>NP</b>	2	5	..	*1759.31	31.60	Biktarvy [GI]

## ▪ DARUNAVIR + COBICISTAT

### **Authority required (STREAMLINED)**

**6413**

Human immunodeficiency virus (HIV) infection

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

**Authority required (STREAMLINED)**

**6428**

Human immunodeficiency virus (HIV) infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

**Authority required (STREAMLINED)**

**6377**

Human immunodeficiency virus (HIV) infection


**Clinical criteria:**

- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- The treatment must not be in combination with ritonavir, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

**darunavir 800 mg + cobicistat 150 mg tablet, 30**

10903W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*940.15	31.60	Prezcobix [JC]

▪ **DARUNAVIR + COBICISTAT + EMTRICITABINE + TENOFOVIR ALAFENAMIDE**

**Note** The cobicistat component of the darunavir + cobicistat combination product provides the necessary pharmacokinetic enhancement of darunavir to achieve therapeutic levels of darunavir.

**Authority required (STREAMLINED)**

**10324**

HIV infection

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner.

**Clinical criteria:**

- Patient must be antiretroviral treatment naive; OR
- Patient must have experienced virological failure or clinical failure or genotypic resistance after at least one antiretroviral regimen, **AND**
- The treatment must not be in combination with ritonavir.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

**Authority required (STREAMLINED)**

**10317**

HIV infection

Treatment Phase: Continuing treatment


**Treatment criteria:**

- Must be treated by a medical practitioner or an authorised nurse practitioner in consultation with a medical practitioner.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must not be in combination with ritonavir.

**darunavir 800 mg + cobicistat 150 mg + emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30**

11955F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	5	..	*1801.07	31.60	Symtuza [JC]

▪ **DOLUTEGRAVIR + ABACAVIR + LAMIVUDINE**

**Authority required (STREAMLINED)**

**9981**

HIV infection

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

**10116**

HIV infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**dolutegravir 50 mg + abacavir 600 mg + lamivudine 300 mg tablet, 30**

10345L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1439.89	31.60	Triumeq [VI]

▪ **DOLUTEGRAVIR + LAMIVUDINE**

**Authority required (STREAMLINED)**

**9987**

HIV infection

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- Patient must not have suspected resistance to either antiretroviral component.

**Authority required (STREAMLINED)**

**11066**

HIV infection

Treatment Phase: Continuing or change of treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**dolutegravir 50 mg + lamivudine 300 mg tablet, 30**

11843H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1350.99	31.60	Dovato [VI]

▪ **DOLUTEGRAVIR + RILPIVIRINE**

**Authority required (STREAMLINED)**

**8214**

HIV infection

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be virologically suppressed on a stable antiretroviral regimen for at least 6 months, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**Authority required (STREAMLINED)**

**8226**

HIV infection

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

**dolutegravir 50 mg + rilpivirine 25 mg tablet, 30**

11540J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1649.29	31.60	Juluca [VI]

▪ **EMTRICITABINE + RILPIVIRINE + TENOFOVIR ALAFENAMIDE**

**Authority required (STREAMLINED)**

**4522**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)**

**4470**

HIV infection

HSD  
(Community)

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**emtricitabine 200 mg + rilpivirine 25 mg + tenofovir alafenamide 25 mg tablet, 30**

11104K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1868.99	31.60	Odefsey [GI]

▪ **EMTRICITABINE + TENOFOVIR ALAFENAMIDE**

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**emtricitabine 200 mg + tenofovir alafenamide 10 mg tablet, 30**

11099E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1378.79	31.60	Descovy [GI]

**emtricitabine 200 mg + tenofovir alafenamide 25 mg tablet, 30**

11113X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1378.79	31.60	Descovy [GI]

▪ **LAMIVUDINE + ZIDOVUDINE**

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

**lamivudine 150 mg + zidovudine 300 mg tablet, 60**

10284G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*170.81	31.60	<sup>a</sup> Combivir [VI]	<sup>a</sup> Lamivudine/Zidovudine Viatrix 150/300 [AL]

▪ **LOPINAVIR + RITONAVIR**

**Authority required (STREAMLINED)**

**4512**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

**Authority required (STREAMLINED)**

**4454**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

## ANTIINFECTIVES FOR SYSTEMIC USE

### lopinavir 400 mg/5 mL + ritonavir 100 mg/5 mL oral liquid, 60 mL

10327M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	10	5	..	*856.37	31.60	Kaletra [VE]

### lopinavir 200 mg + ritonavir 50 mg tablet, 120

10272P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*908.83	31.60	Kaletra [VE]

## ■ TENOFOVIR ALAFENAMIDE + EMTRICITABINE + ELVITEGRAVIR + COBICISTAT

### Authority required (STREAMLINED)

**4522**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive.

### Authority required (STREAMLINED)

**4470**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection.

### tenofovir alafenamide 10 mg + emtricitabine 200 mg + elvitegravir 150 mg + cobicistat 150 mg tablet, 30

11114Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*1868.99	31.60	Genvoya [GI]

## ■ TENOFOVIR DISOPROXIL + EMTRICITABINE

**Note** Pharmaceutical benefits that have the forms tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet, and tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg tablet are equivalent for the purposes of substitution.

**Note** In the case of a shortage, pharmaceutical benefits that have the brand Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA) can be substituted for pharmaceutical benefits that have the forms tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg tablet, tenofovir disoproxil fumarate 300 mg with emtricitabine 200 mg tablet and tenofovir disoproxil succinate 301 mg with emtricitabine 200 mg tablet.

### Authority required (STREAMLINED)

**6985**

HIV infection

Treatment Phase: Initial

#### Clinical criteria:

- Patient must be antiretroviral treatment naive, **AND**
- The treatment must be in combination with other antiretroviral agents.

### Authority required (STREAMLINED)

**6986**

HIV infection

Treatment Phase: Continuing

#### Clinical criteria:

- Patient must have previously received PBS-subsidised therapy for HIV infection, **AND**
- The treatment must be in combination with other antiretroviral agents.

### tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

10347N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*52.67	31.60	<sup>a</sup> CIPLA TENOFOVIR + EMTRICITABINE 300/200 [LR]	<sup>a</sup> TENOFOVIR/EMTRICITABINE 300/200 ARX [XT]

### tenofovir disoproxil fumarate 300 mg + emtricitabine 200 mg tablet, 30

14637J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*187.11	31.60	<sup>a</sup> Emtricitabine and Tenofovir Disoproxil Fumarate 200 mg/300 mg Tablets (Laurus Labs, USA) [KQ]

### tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg tablet, 30

11149T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*45.09	31.60	<sup>a</sup> Tenofovir Disoproxil Emtricitabine Viatris 300/200 [AL]



**tenofovir disoproxil succinate 301 mg + emtricitabine 200 mg tablet, 30**

12506F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*45.09	31.60	<sup>a</sup> Tenofovir/Emtricitabine Sandoz 301/200 [SZ]

**■ TENOFOVIR DISOPROXIL + EMTRICITABINE + EFAVIRENZ****Authority required (STREAMLINED)****4522**

HIV infection

Treatment Phase: Initial

**Clinical criteria:**

- Patient must be antiretroviral treatment naive.

**Authority required (STREAMLINED)****4470**

HIV infection

Treatment Phase: Continuing

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy for HIV infection.

**tenofovir disoproxil maleate 300 mg + emtricitabine 200 mg + efavirenz 600 mg tablet, 30**

11732L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	2	5	..	*291.43	31.60	Tenofovir Disoproxil Emtricitabine Efavirenz Viatris 300/200/600 [AL]

*Other antivirals***■ MARAVIROC****Authority required (STREAMLINED)****5008**

HIV infection

**Clinical criteria:**

- Patient must be infected with CCR5-tropic HIV-1, **AND**
- The treatment must be in addition to optimised background therapy, **AND**
- The treatment must be in combination with other antiretroviral agents, **AND**
- Patient must have experienced virological failure or clinical failure or genotypic resistance after each of at least 3 different antiretroviral regimens that have included one drug from at least 3 different antiretroviral classes.

Virological failure is defined as a viral load greater than 400 copies per mL on two consecutive occasions, while clinical failure is linked to emerging signs and symptoms of progressing HIV infection or treatment-limiting toxicity.

A tropism assay to determine CCR5 only strain status must be performed prior to initiation. Individuals with CXCR4 tropism demonstrated at any time point are not eligible.

**maraviroc 150 mg tablet, 60**

10318C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*1225.63	31.60	<sup>a</sup> Celsentri [VI]	<sup>a</sup> Maraviroc Waymade [IX]

**maraviroc 300 mg tablet, 60**

10355B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
NP	2	5	..	*1225.63	31.60	<sup>a</sup> Celsentri [VI]	<sup>a</sup> Maraviroc Waymade [IX]

**■ NERVOUS SYSTEM****■ PSYCHOLEPTICS****ANTIPSYCHOTICS***Diazepines, oxazepines, thiazepines and oxepines***■ CLOZAPINE**

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Pfizer ClopineCentral.

**Authority required (STREAMLINED)****4998**

Schizophrenia

Treatment Phase: Continuing treatment

**Treatment criteria:**

- Must be treated by a psychiatrist; OR
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

**Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**

## NERVOUS SYSTEM

- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

### clozapine 50 mg/mL oral liquid, 100 mL

11422E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	‡1	..	..	149.07	31.60	Versacloz [PF]

### ■ CLOZAPINE

**Note** Patients receiving clozapine under the PBS listing must be registered in the clozapine patient monitoring program relevant for the brand of clozapine being prescribed and dispensed: Novartis Clozaril Patient Monitoring System (eCPMS), Pfizer ClopineCentral or Juno Connected Clozitor.

#### **Authority required (STREAMLINED)**

**4998**

Schizophrenia

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Must be treated by a psychiatrist; OR
- Must be treated by an authorised medical practitioner, with the agreement of the treating psychiatrist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy with this drug for this condition, **AND**
- Patient must have completed at least 18 weeks therapy, **AND**
- Patient must be on a clozapine dosage considered stable by a treating psychiatrist, **AND**
- The treatment must be under the supervision and direction of a psychiatrist reviewing the patient at regular intervals. A medical practitioner should request a quantity sufficient for up to one month's supply. Up to 5 repeats will be authorised.

### clozapine 50 mg/mL oral liquid, 100 mL

10341G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	149.07	31.60	Clopine Suspension [PF]

### clozapine 100 mg tablet, 100

10358E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*225.07	31.60	Clopine 100 [PF] Clozitor [JU]	Clozaril 100 [GO]

### clozapine 200 mg tablet, 100

10288L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*441.47	31.60	Clopine 200 [PF]	Clozitor [JU]

### clozapine 25 mg tablet, 100

10289M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*68.17	31.60	Clopine 25 [PF] Clozitor [JU]	Clozaril 25 [GO]

### clozapine 50 mg tablet, 100

10302F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*124.09	31.60	Clopine 50 [PF]	Clozitor [JU]

## ■ OTHER NERVOUS SYSTEM DRUGS

### DRUGS USED IN ADDICTIVE DISORDERS

*Drugs used in opioid dependence*

### ■ BUPRENORPHINE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

#### **Authority required (STREAMLINED)**

**16009**

Opioid dependence

#### **Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment. The prescriber must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. The maximum listed quantity or number of repeats must not be prescribed if lesser quantity or repeats are sufficient for the patient's needs.

### buprenorphine 400 microgram sublingual tablet, 7

13310M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	5	..	*35.96	31.60	Subutex [IR]

NP

**buprenorphine 2 mg sublingual tablet, 7**

13336X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	12	5	..	*119.88	31.60	Subutex [IR]

**buprenorphine 8 mg sublingual tablet, 7**

13337Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	16	5	..	*413.24	31.60	Subutex [IR]

**■ BUPRENORPHINE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

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

**Authority required (STREAMLINED)****16015**

Opioid dependence

**Treatment criteria:**

- Must be treated by a health care professional.

**Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment, **AND**
  - Patient must be stabilised on one of the following prior to commencing treatment with this drug for this condition: (i) weekly prolonged release buprenorphine (Buvidal Weekly) (ii) sublingual buprenorphine (iii) buprenorphine/naloxone.
- The prescriber must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.

**buprenorphine 96 mg/0.27 mL modified release injection, 0.27 mL syringe**

13309L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	379.20	31.60	Buvidal Monthly [UR]

**buprenorphine 128 mg/0.36 mL modified release injection, 0.36 mL syringe**

13302D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	379.20	31.60	Buvidal Monthly [UR]

**buprenorphine 64 mg/0.18 mL modified release injection, 0.18 mL syringe**

13298X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	379.20	31.60	Buvidal Monthly [UR]

**buprenorphine 160 mg/0.45 mL modified release injection, 0.45 mL syringe**

13303E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	1	5	..	379.20	31.60	Buvidal Monthly [UR]

**■ BUPRENORPHINE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

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

**Authority required (STREAMLINED)****16050**

Opioid dependence

**Treatment criteria:**

- Must be treated by a health care professional.

**Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment, **AND**
- Patient must be stabilised on sublingual buprenorphine or buprenorphine/naloxone prior to commencing treatment with this drug for this condition.

The prescriber must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.

**buprenorphine 100 mg/0.5 mL modified release injection, 0.5 mL syringe**

13320C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	379.20	31.60	Sublocade [IR]

**buprenorphine 300 mg/1.5 mL modified release injection, 1.5 mL syringe**

13327K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
NP	±1	5	..	379.20	31.60	Sublocade [IR]

**■ BUPRENORPHINE**

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

# NERVOUS SYSTEM

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

## **Authority required (STREAMLINED)**

**16051**

Opioid dependence

### **Treatment criteria:**

- Must be treated by a health care professional.

### **Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment.

The prescriber must not request the maximum listed quantity or number of repeats if lesser quantity or repeats are sufficient for the patient's needs.

### **buprenorphine 16 mg/0.32 mL modified release injection, 0.32 mL syringe**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13297W	4	5	..	*379.20	31.60	Buvidal Weekly [UR]

NP

### **buprenorphine 24 mg/0.48 mL modified release injection, 0.48 mL syringe**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13296T	4	5	..	*379.20	31.60	Buvidal Weekly [UR]

NP

### **buprenorphine 32 mg/0.64 mL modified release injection, 0.64 mL syringe**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13314R	4	5	..	*379.20	31.60	Buvidal Weekly [UR]

NP

### **buprenorphine 8 mg/0.16 mL modified release injection, 0.16 mL syringe**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13328L	4	5	..	*379.20	31.60	Buvidal Weekly [UR]

NP

## ■ BUPRENORPHINE + NALOXONE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

## **Authority required (STREAMLINED)**

**16009**

Opioid dependence

### **Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment.

The prescriber must request a quantity sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. The maximum listed quantity or number of repeats must not be prescribed if lesser quantity or repeats are sufficient for the patient's needs.

### **buprenorphine 2 mg + naloxone 500 microgram sublingual film, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13322E	3	5	..	*158.19	31.60	Suboxone Film 2/0.5 [IR]

NP

### **buprenorphine 8 mg + naloxone 2 mg sublingual film, 28**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
13321D	4	5	..	*509.92	31.60	Suboxone Film 8/2 [IR]

NP

## ■ METHADONE

**Note** Care must be taken to comply with the provisions of State/Territory law when prescribing this drug.

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

## **Authority required (STREAMLINED)**

**16083**

Opioid dependence

### **Clinical criteria:**

- The treatment must be within a framework of medical, social and psychological treatment.

The prescriber must request a quantity (in millilitres) sufficient for up to 28 days of supply per dispensing according to the patient's daily dose. Up to 5 repeats will be authorised. The maximum listed quantity or number of repeats must not be prescribed if lesser quantity or repeats are sufficient for the patient's needs.

### **methadone hydrochloride 5 mg/mL oral liquid, 200 mL**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13334T	4.2	5	..	*50.58	31.60	<sup>a</sup> Aspen Methadone Syrup [AS]	<sup>a</sup> Biodone Forte [MW]

NP

### **methadone hydrochloride 5 mg/mL oral liquid, 1 L**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
13333R	0.84	5	..	*44.72	31.60	<sup>a</sup> Aspen Methadone Syrup [AS]	<sup>a</sup> Biodone Forte [MW]

NP

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# Botulinum Toxin Program

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▪ **MUSCULO-SKELETAL SYSTEM**

▪ **MUSCLE RELAXANTS**

**MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS**

*Other muscle relaxants, peripherally acting agents*

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5221**

Blepharospasm or hemifacial spasm

**Clinical criteria:**

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**Population criteria:**

- Patient must be aged 12 years or older.

**botulinum toxin type A 100 units injection, 1 vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
10997T	4	..	..	*1098.67	31.60	Botox [VE]

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5406**

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

**botulinum toxin type A 100 units injection, 1 vial**

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
11023E	4	..	..	*1098.67	31.60	Botox [VE]

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**5409**

Urinary incontinence

**Clinical criteria:**

- The condition must be due to neurogenic detrusor overactivity, as demonstrated by urodynamic study, **AND**
- The condition must be inadequately controlled by anti-cholinergic therapy, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with Botulinum Toxin Type A Neurotoxin Complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment, **AND**
- Patient must have multiple sclerosis; OR
- Patient must have a spinal cord injury; OR
- Patient must be aged 18 years or older and have spina bifida.

**Treatment criteria:**

- Must be treated by a urologist; OR

- Must be treated by a urogynaecologist.

**botulinum toxin type A 100 units injection, 1 vial**

10993N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1098.67	31.60	Botox [VE]

**▪ BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)****5359**

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**Authority required (STREAMLINED)****8822**

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**botulinum toxin type A 100 units injection, 1 vial**

10998W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1098.67	31.60	Botox [VE]

**▪ BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)****5178**

Moderate to severe spasticity of the upper limb

**Clinical criteria:**

- Patient must have cerebral palsy.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

**Authority required (STREAMLINED)****8929**

Moderate to severe spasticity of the upper limb

**Clinical criteria:**

- Patient must have cerebral palsy.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR

## MUSCULO-SKELETAL SYSTEM

- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

### botulinum toxin type A 100 units injection, 1 vial

10999X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1098.67	31.60	Botox [VE]

#### ▪ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** Special Pricing Arrangements apply.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

#### Authority required (STREAMLINED)

**11784**

Chronic migraine

#### **Treatment criteria:**

- Must be treated by a neurologist.

#### **Clinical criteria:**

- Patient must have experienced an average of 15 or more headache days per month, with at least 8 days of migraine, over a period of at least 6 months, prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have experienced an inadequate response, intolerance or a contraindication to at least three prophylactic migraine medications prior to commencement of treatment with botulinum toxin type A neurotoxin, **AND**
- Patient must have achieved and maintained a 50% or greater reduction from baseline in the number of headache days per month after two treatment cycles (each of 12 weeks duration) in order to be eligible for continuing PBS-subsidised treatment, **AND**
- Patient must be appropriately managed by his or her practitioner for medication overuse headache, prior to initiation of treatment with botulinum toxin.

#### **Population criteria:**

- Patient must be aged 18 years or older.

Prophylactic migraine medications are propranolol, amitriptyline, pizotifen, candesartan, verapamil, nortriptyline, sodium valproate or topiramate.

### botulinum toxin type A 100 units injection, 1 vial

11000Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1098.67	31.60	Botox [VE]

#### ▪ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)

**6953**

Urinary incontinence

#### **Treatment criteria:**

- Must be treated by a urologist; OR
- Must be treated by a gynaecologist.

#### **Clinical criteria:**

- The condition must be due to idiopathic overactive bladder, **AND**
- The condition must have been inadequately controlled by therapy involving at least two alternative anti-cholinergic agents, **AND**
- Patient must experience at least 14 episodes of urinary incontinence per week prior to commencement of treatment with botulinum toxin type A neurotoxin complex, **AND**
- Patient must be willing and able to self-catheterise, **AND**
- The treatment must not continue if the patient does not achieve a 50% or greater reduction from baseline in urinary incontinence episodes 6-12 weeks after the first treatment.

#### **Population criteria:**

- Patient must be aged 18 years or older.

### botulinum toxin type A 100 units injection, 1 vial

11004E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1098.67	31.60	Botox [VE]

#### ▪ BOTULINUM TOXIN TYPE A

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

#### Authority required (STREAMLINED)



**5408**

Severe primary axillary hyperhidrosis

**Clinical criteria:**

- Patient must have previously failed topical aluminium chloride hexahydrate after one to two months of treatment; OR
- Patient must be intolerant to topical aluminium chloride hexahydrate treatment.

**Population criteria:**

- Patient must be aged 12 years or older.

**Treatment criteria:**

- Must be treated by a dermatologist; OR
- Must be treated by a neurologist; OR
- Must be treated by a paediatrician.

Maximum number of treatments per year is 3, with no less than 4 months to elapse between treatments.

**botulinum toxin type A 100 units injection, 1 vial**

11016T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1098.67	31.60	Botox [VE]

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** Special Pricing Arrangements apply.

**Note** An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

**Authority required (STREAMLINED)**

**9334**

Moderate to severe spasticity of the lower limb following an acute event

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the lower limb/s following stroke or other acute neurological event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating of at least 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**
- Patient must not have established severe contracture in the limb to be treated, **AND**
- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per lower limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per lower limb each year thereafter.

**Population criteria:**

- Patient must be aged 18 years or older.
- Standard management includes physiotherapy and/or oral spasticity agents.

**botulinum toxin type A 100 units injection, 1 vial**

11751L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1098.67	31.60	Botox [VE]

▪ **BOTULINUM TOXIN TYPE A**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**9547**

Moderate to severe spasticity of the upper limb following an acute event

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**

## MUSCULO-SKELETAL SYSTEM

- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter,

**AND**

- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

Standard management includes physiotherapy and/or oral spasticity agents.

**botulinum toxin type A 100 units injection, 1 vial**

12017L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1098.67	31.60	Botox [VE]

▪ **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5405**

Blepharospasm or hemifacial spasm

**Clinical criteria:**

- Patient must have blepharospasm; OR
- Patient must have hemifacial spasm.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

11022D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*855.99	31.60	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

10987G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*958.79	31.60	Dysport [IS]

▪ **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5406**

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

11015R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*855.99	31.60	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

11007H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*958.79	31.60	Dysport [IS]

▪ **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5178**

Moderate to severe spasticity of the upper limb

**Clinical criteria:**

- Patient must have cerebral palsy.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

**Authority required (STREAMLINED)**

**8929**

Moderate to severe spasticity of the upper limb

**Clinical criteria:**

- Patient must have cerebral palsy.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

12178Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*855.99	31.60	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

12214W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*958.79	31.60	Dysport [IS]

**■ CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5359**

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**

- Patient must be aged from 2 to 17 years inclusive.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**Authority required (STREAMLINED)**

**8822**

Dynamic equinus foot deformity

**Clinical criteria:**

- The condition must be due to spasticity, **AND**
- Patient must have cerebral palsy, **AND**
- Patient must be ambulant.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a paediatrician; OR
- Must be treated by a rehabilitation specialist.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

11006G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*855.99	31.60	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

10981Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*958.79	31.60	Dysport [IS]

■ **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**9547**

Moderate to severe spasticity of the upper limb following an acute event

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**
- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter,

**AND**

- Patient must not have established severe contracture in the limb to be treated.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

Standard management includes physiotherapy and/or oral spasticity agents.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

10988H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*855.99	31.60	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

10982B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*958.79	31.60	Dysport [IS]

■ **CLOSTRIDIUM BOTULINUM TYPE A TOXIN-HAEMAGGLUTININ COMPLEX**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**9334**

Moderate to severe spasticity of the lower limb following an acute event

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

**Clinical criteria:**

- The condition must be moderate to severe spasticity of the lower limb/s following stroke or other acute neurological event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**

- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating of at least 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**
- Patient must not have established severe contracture in the limb to be treated, **AND**
- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per lower limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per lower limb each year thereafter.

**Population criteria:**

- Patient must be aged 18 years or older.
- Standard management includes physiotherapy and/or oral spasticity agents.

**clostridium botulinum type A toxin-haemagglutinin complex 500 units injection, 1 vial**

11857C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*1270.77	31.60	Dysport [IS]

**clostridium botulinum type A toxin-haemagglutinin complex 300 units injection, 1 vial**

11831Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1190.62	31.60	Dysport [IS]

▪ **INCOBOTULINUMTOXINA**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5360**

Blepharospasm

**Clinical criteria:**

- Patient must have blepharospasm.

**Population criteria:**

- Patient must be aged 18 years or older.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by an ophthalmologist; OR
- Must be treated by an otolaryngology head and neck surgeon; OR
- Must be treated by a plastic surgeon.

**incobotulinumtoxinA 100 units injection, 1 vial**

10994P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1402.43	31.60	Xeomin [EJ]

▪ **INCOBOTULINUMTOXINA**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Authority required (STREAMLINED)**

**5222**

Spasmodic torticollis

**Clinical criteria:**

- Patient must have spasmodic torticollis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be as adjunctive therapy to current standard care.

**Treatment criteria:**

- Must be treated by a neurologist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a rehabilitation specialist.

**Population criteria:**

- Patient must be aged 18 years or older.

**incobotulinumtoxinA 100 units injection, 1 vial**

11005F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1402.43	31.60	Xeomin [EJ]

▪ **INCOBOTULINUMTOXINA**

**Caution** Contraindications to treatment include known sensitivity to botulinum toxin.

**Note** The units used to express the potency of botulinum toxin preparations currently available for PBS subsidy are not equivalent.

**Note** An acute event may be a clinical or external event that leads to upper motor neuron lesions resulting in spasticity for example stroke, traumatic brain injury, spinal cord injury, infection or hypoxia.

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**9547**

Moderate to severe spasticity of the upper limb following an acute event

## MUSCULO-SKELETAL SYSTEM

### Clinical criteria:

- The condition must be moderate to severe spasticity of the upper limb/s following an acute event, defined as a Modified Ashworth Scale rating of 3 or more, **AND**
- The treatment must only be used as second line therapy when standard management has failed; OR
- The treatment must only be used as an adjunct to physical therapy, **AND**
- The treatment must not continue if the patient does not respond (defined as not having had a decrease in spasticity rating greater than 1, using the Modified Ashworth Scale, in at least one joint) after two treatment periods (with any botulinum toxin type A), **AND**
- The treatment must not exceed a maximum of 4 treatment periods (with any botulinum toxin type A) per upper limb in the first year of treatment, and 2 treatment periods (with any botulinum toxin type A) per upper limb each year thereafter,

### AND

- Patient must not have established severe contracture in the limb to be treated.

### Population criteria:

- Patient must be aged 18 years or older.

### Treatment criteria:

- Must be treated by a neurologist; OR
- Must be treated by an orthopaedic surgeon; OR
- Must be treated by a rehabilitation specialist; OR
- Must be treated by a plastic surgeon; OR
- Must be treated by a geriatrician.

Standard management includes physiotherapy and/or oral spasticity agents.

### incobotulinumtoxinA 100 units injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
12087E	4	..	..	*1402.43	31.60	Xeomin [EJ]

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# Growth Hormone Program

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## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

#### ANTERIOR PITUITARY LOBE HORMONES AND ANALOGUES

##### *Somatropin and somatropin agonists*

#### MECASERMIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** The PBS authority application administrator will approve a maximum quantity of vials in line with the following formula (based on the upper dose range of 0.12 mg/kg dosed twice daily, one vial containing 40 mg of drug and target supply duration of 30 days per dispensing):

Number of vials equals 7.2 multiplied by weight (kg) divided by 40. For ease of reference, this equates to:

Below 16 kg: up to 3 vials

16 to 22 kg: up to 4 vials

22 to 27 kg: up to 5 vials

27 to 33 kg: up to 6 vials

33 to 38 kg: up to 7 vials

38 to 44 kg: up to 8 vials

Beyond 44 kg: refer to above formula

#### **Authority required**

Severe growth failure with primary insulin-like growth factor-1 deficiency

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- The condition must be caused by severe primary insulin-like growth factor-1 deficiency (IGFD), with IGFD deficiency for the purpose of PBS subsidy defined as a basal IGF-1 level (measured any time prior to initiating treatment with this drug) below the 2.5<sup>th</sup> percentile adjusted for each of: (i) age, (ii) gender, **AND**
- The condition must have resulted in the patient experiencing short stature, with short stature for the purpose of PBS subsidy defined as the patient's height (measured any time prior to initiating treatment with this drug) being at least 3 standard deviations below the norm, adjusted for each of: (i) age, (ii) gender, **AND**
- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child), **AND**
- The condition must not be caused by growth hormone deficiency, **AND**
- Patient must have a bone age of less than 13.5 years (females); **OR**
- Patient must have a bone age of less than 15.5 years (males), **AND**
- The condition must not be caused by secondary causes of IGFD - prior to initiating treatment with this drug, the treating physician has at least excluded each of the following: (i) malnutrition, (ii) hypopituitarism, (iii) hypothyroidism, (iv) medication side effects, **AND**
- The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing).

#### **Treatment criteria:**

- Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; **OR**
- Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician.

#### **Population criteria:**

- Patient must be aged from 2 years up until their 18<sup>th</sup> birthday.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The initial treatment authority application must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include the following:

(1) Insulin-like growth factor-1 deficiency:

State each of: (a) the patient's most recent basal IGF-1 level measured (ng/mL), (b) the measurement date (dd/mm/yy), (c) the name of the pathology result provider;

(2) Short stature:

State the patient's height (cm);

(3) Normal growth hormone levels:

State the patient's most recent growth hormone level measurement (mcg/L) - this figure must be greater than 6.6 mcg/L;



(4) Bone age: (where the patient has a chronological age of at least 2.5 years):  
State each of: (a) the patient's bone age in numerical figures at the time when it was most recently determined, (b) the date (dd/mm/yy) of this determination that is within 12 months of this authority application;

(5) The patient's weight (kg);

(6) The prescribed dose (mg/kg) (between 0.04 to 0.12);

(7) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.

Height, growth velocity and weight measurements must not be more than three months old at the time of application.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** The Centers for Disease Control and Prevention (U.S. Department of Health & Human Services) publishes Clinical Growth Charts which this restriction refers to. Both the 'length-for-age' (birth to 36 months) and 'stature-for-age' (children 2 years to 20 years) growth charts can be viewed, printed and reproduced via the following website link:  
[https://www.cdc.gov/growthcharts/clinical\\_charts.htm](https://www.cdc.gov/growthcharts/clinical_charts.htm)

**Authority required**

Severe growth failure with primary insulin-like growth factor-1 deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have a bone age of less than 13.5 years (females); **OR**
- Patient must have a bone age of less than 15.5 years (males), **AND**
- The treatment must not be in a patient with known epiphyseal closure/growth plate fusion (i.e. the patient is known to have ceased growing), **AND**
- The condition must be responsive to this drug treatment as evidenced by each of: (i) patient is showing catch-up for height standard deviation score against Laron syndrome (growth hormone insensitivity syndrome) growth charts, (ii) patient has a growth velocity of greater than 2 cm per year (extrapolated for time on treatment) at the time of this continuing authority application; **OR**
- The condition must be yet to respond to this drug treatment only for the reason of sub-optimal dosing.

**Treatment criteria:**

- Must be treated by a paediatric endocrinologist; the authority application must be completed by this physician type; **OR**
- Must be treated by a paediatrician who has consulted the above mentioned specialist type; the authority application must be completed by this paediatrician.

**Population criteria:**

- Patient must be aged from 2 years up until their 18<sup>th</sup> birthday.

The continuing treatment authority application must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

(1) The patient's height (cm);

(2) Where this authority application seeks to continue treatment where there has been an inadequate response to treatment due to sub-optimal dosing, state each of:

(i) the most recently prescribed dose (mg/kg) that resulted in an inadequate response;

(ii) the dose (mg/kg) (between 0.04 to 0.12) that was/will be subsequently prescribed to address the inadequate response;

(3) The patient's weight (kg);

(4) The patient's growth velocity in response to the preceding supply of drug (cm/year; extrapolated for time on treatment);

(5) The number of vials rounded to the nearest whole number, to provide sufficient drug quantity for 30 days of treatment per dispensing - see the relevant 'NOTE' attached to this listing for guidance.

Height, growth velocity and weight measurements must not be more than three months old at the time of application.

Document growth improvements in the patient's medical records.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

**Note** Laron syndrome growth charts are those appearing in the following publication:

Laron Z, Lilos P, Klinger B. Growth Curves for Laron syndrome. **Arch Dis Child**. 1993;68(6):768-770.

This literature article can be accessed through the following website link:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1029371>

**mecasermin 10 mg/mL injection, 4 mL vial**

13116H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	1072.67	31.60	Increlex [IS]

▪ **SOMATROGON**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system

(see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Note that the 60 mg pen is limited to dose increments of 0.5 mg and a maximum delivered dose of 30 mg, while the 24 mg pen is limited to 0.2 mg increments and a maximum delivered dose of 12 mg. Rounding (up or down) the weekly dose in mg is permitted to the nearest multiple of 0.5 or 0.2. Note that once opened, a pen is to be discarded after 28 days. Give consideration to strengths and combinations that minimise drug wastage.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 16 weeks of treatment per dispensing based on the Product Information recommended dosing of 0.66 mg/kg/week. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 32 weeks of treatment. See the table located on the following webpage which lists a range of patient weights (kg) and the corresponding number of units and combination of strengths to be sought in an authority application:  
<https://www.pbs.gov.au/browse/section100-gh>

### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**

• Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; or  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.
3. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

### **Treatment criteria:**

- Patient must be undergoing recommencing treatment following a temporary treatment break (i.e. a lapse) from this drug for the stated indication above - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication.

### **Clinical criteria:**

- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not be for the purposes of resuming treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Recent growth data (height and weight, not older than three months).
2. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Treatment criteria:**

- Patient must be undergoing treatment that is simultaneously: (a) recommencing treatment following a temporary break in treatment (i.e. a lapse), plus (b) reclassifying the PBS indication whilst continuing with the same growth hormone; subsidy

through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication where the most recent authority approval was for a different growth hormone.

**Clinical criteria:**

- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment); OR  
 (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age plus sex immediately prior to commencing treatment.
2. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations.

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.

4. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex, **AND**
- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.
3. Confirmation of the patient's maturational or constitutional delay status.
4. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1<sup>st</sup> adult height percentile.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment

**Treatment criteria:**

- Patient must be undergoing recommencing treatment following a temporary treatment break (i.e. a lapse) from this drug for the stated indication above - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication.

**Clinical criteria:**

- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not be for the purposes of resuming treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Recent growth data (height and weight, not older than three months).
2. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Patient must be undergoing treatment that is simultaneously: (a) recommencing treatment following a temporary break in treatment (i.e. a lapse), plus (b) reclassifying the PBS indication whilst continuing with the same growth hormone; subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) reclassify the PBS indication where the most recent authority approval was for a different growth hormone.

**Clinical criteria:**

- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose, **AND**
- Patient must have had a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time treatment first commenced, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age plus sex measured over a 12 month interval (or a 6 month interval for an older child) prior to having commenced treatment; OR
- Patient must have had an annual growth velocity of no higher than 8 cm per year where the patient had either a bone/chronological age no higher than 2.5 years prior to having commenced treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where the patient had a chronological age greater than 2.5 years at commencement of treatment.

2. Recent growth data (height and weight, not older than three months).

3. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### somatrogon 60 mg/1.2 mL injection, 1.2 mL pen device

13120M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	945.97	31.60	Ngenla [PF]

### somatrogon 24 mg/1.2 mL injection, 1.2 mL pen device

13119L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	383.59	31.60	Ngenla [PF]

## ▪ SOMATROGON

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos))

Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Note** An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. Note that the 60 mg pen is limited to dose increments of 0.5 mg and a maximum delivered dose of 30 mg, while the 24 mg pen is limited to 0.2 mg increments and a maximum delivered dose of 12 mg. Rounding (up or down) the weekly dose in mg is permitted to the nearest multiple of 0.5 or 0.2. Note that once opened, a pen is to be discarded after 28 days. Give consideration to strengths and combinations that minimise drug wastage.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 13 weeks of treatment per dispensing based on the Product Information recommended dosing of 0.66 mg/kg/week. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 26 weeks of treatment. See the table located on the following webpage which lists a range of patient weights (kg) and the corresponding number of units and combination of strengths to be sought in an authority application:

<https://www.pbs.gov.au/browse/section100-gh>

#### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

#### **Treatment criteria:**

- Patient must be undergoing continuing PBS-subsidised therapy with this drug - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication.

#### **Clinical criteria:**

- Patient must have achieved the 50<sup>th</sup> percentile growth velocity for bone age plus sex following the most recent supply; OR
- Patient must have achieved an increase in height standard deviation score for chronological age plus sex following the most recent supply; OR

- Patient must have achieved a minimum growth velocity of 4 cm per year following the most recent supply; OR
- Patient must have achieved a mid-parental height standard deviation score following the most recent supply; OR
- The treatment must have been administered at a dose that is lower than that recommended in the approved Product Information in the most recent supply, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:
  1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
  2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.
  3. The final adult height (in cm) of the patient's mother and father (where available).

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Change of drug

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

**Clinical criteria:**

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

**Definition:**

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and



(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

### **Treatment criteria:**

- Patient must be undergoing continuing PBS-subsidised therapy with this drug where the most recent authority approval for this drug was for a different PBS indication to that stated above - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication where the most recent authority approval was for a different growth hormone, (v) reclassify the PBS indication and recommence treatment simultaneously.

### **Clinical criteria:**

- The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment); OR
- (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age plus sex immediately prior to commencing treatment.
2. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations.
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
4. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

### **Treatment criteria:**

- Patient must be undergoing privately funded treatment (e.g. through a clinical trial, a sponsor compassionate access program, supply from an overseas jurisdiction) with this drug at the time of this authority application - subsidy through this treatment phase must only occur once per lifetime.

### **Clinical criteria:**

- The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment); OR

(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age plus sex immediately prior to commencing treatment.

2. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations.

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.

4. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.

If the application is submitted through HPOS form upload or mail, it must include:

(i) A completed authority prescription form; and

(ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

### **Treatment criteria:**

- Patient must be undergoing continuing PBS-subsidised therapy with this drug - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication.

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have achieved the 50<sup>th</sup> percentile growth velocity for bone age plus sex following the most recent supply; OR
- Patient must have achieved an increase in height standard deviation score for chronological age plus sex following the most recent supply; OR
- Patient must have achieved a minimum growth velocity of 4 cm per year following the most recent supply; OR
- Patient must have achieved a mid-parental height standard deviation score following the most recent supply; OR
- The treatment must have been administered at a dose that is lower than that recommended in the approved Product Information in the most recent supply, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:
  1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
  2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.
  3. The final adult height (in cm) of the patient's mother and father (where available).

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature and slow growth

Treatment Phase: Change of drug

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

**Clinical criteria:**

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

Definition:

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

### **Treatment criteria:**

- Patient must be undergoing continuing PBS-subsidised therapy with this drug where the most recent authority approval for this drug was for a different PBS indication to that stated above - subsidy through this treatment phase must not: (i) initiate treatment, (ii) change the prescribed drug, (iii) recommence treatment, (iv) reclassify the PBS indication where the most recent authority approval was for a different growth hormone, (v) reclassify the PBS indication and recommence treatment simultaneously.

### **Clinical criteria:**

- The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose, **AND**
- Patient must have had a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time treatment first commenced, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age plus sex measured over a 12 month interval (or a 6 month interval for an older child) prior to having commenced treatment; **OR**
- Patient must have had an annual growth velocity of no higher than 8 cm per year where the patient had either a bone/chronological age no higher than 2.5 years prior to having commenced treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where the patient had a chronological age greater than 2.5 years at commencement of treatment.
2. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
3. A bone age result performed within the last 12 months where a patient has a chronological age greater than 2.5 years.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature and slow growth

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

### **Treatment criteria:**

- Patient must be undergoing privately funded treatment (e.g. through a clinical trial, a sponsor compassionate access program, supply from an overseas jurisdiction) with this drug at the time of this authority application - subsidy through this treatment phase must only occur once per lifetime.

### **Clinical criteria:**

- The treatment must not be for the purposes of continuing treatment that is known to be non-efficacious for the patient - where an inadequate response has been observed for the most recent supply of this drug, it must have been confounded by at least one of the following: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance due to social/family problems, (v) a lower than recommended (as specified by this drug's approved Product Information) dose, **AND**
- Patient must have had a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time treatment first commenced, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age plus sex measured over a 12 month interval (or a 6 month interval for an older child) prior to having commenced treatment; **OR**
- Patient must have had an annual growth velocity of no higher than 8 cm per year where the patient had either a bone/chronological age no higher than 2.5 years prior to having commenced treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment where a patient had a chronological age greater than 2.5 years at commencement of treatment; **OR**

(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age plus sex immediately prior to commencing treatment.

2. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.

3. A bone age result performed within the last 12 months where the patient has chronological age greater than 2.5 years.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**somatrogon 60 mg/1.2 mL injection, 1.2 mL pen device**

13125T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	945.97	31.60	Ngenla [PF]

**somatrogon 24 mg/1.2 mL injection, 1.2 mL pen device**

13130C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	383.59	31.60	Ngenla [PF]

▪ **SOMATROPIN**

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

**Authority required**

Severe growth hormone deficiency

Treatment Phase: Initial treatment of late onset growth hormone deficiency

**Treatment criteria:**

- Must be treated by an endocrinologist.

**Clinical criteria:**

- Patient must have onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease diagnosed at chronological age of 18 years or older; **OR**
- Patient must have onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years, **AND**
- Patient must have a diagnostic insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; **OR**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must have a diagnostic arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; OR
- Patient must have a diagnostic glucagon provocation test with maximum serum GH less than 3 micrograms per litre; OR
- Patient must have: (a) a chronological age of 18 years or older, (b) established hypothalamic-pituitary disease, (c) at least three documented pituitary hormone deficiencies, (d) an IGF-1 concentration lower than the sex- and age-specific lower limit of normal in a patient.

The authority application must be in writing and must include:

1. Details of the proposed prescription; AND
2. A completed Severe Growth Hormone Deficiency supporting information form; AND
3. If applicable, results of the growth hormone simulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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### **Authority required**

Severe growth hormone deficiency

Treatment Phase: Continuing treatment in a person with a mature skeleton or aged 18 years or older

#### **Treatment criteria:**

- Must be treated by an endocrinologist.

#### **Clinical criteria:**

- Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause in a patient with a mature skeleton; OR
- Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease in a patient with chronological age of 18 years or older; OR
- Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years.

**Note** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see [www.servicesaustralia.gov.au/HPOS](http://www.servicesaustralia.gov.au/HPOS)) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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### **Authority required**

Severe growth hormone deficiency

Treatment Phase: Initial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a child

#### **Treatment criteria:**

- Must be treated by an endocrinologist.

#### **Clinical criteria:**

- Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition as a child.

#### **Population criteria:**

- Patient must have a mature skeleton.

Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency.

The authority application must be in writing and must include:

1. Details of the proposed prescription; AND
2. A completed Severe Growth Hormone Deficiency supporting information form.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

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### **Authority required**

Severe growth hormone deficiency

Treatment Phase: Initial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a child

**Treatment criteria:**

- Must be treated by an endocrinologist.

**Clinical criteria:**

- Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause, **AND**
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition as a child, **AND**
- Patient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; **OR**
- Patient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; **OR**
- Patient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre.

**Population criteria:**

- Patient must have a mature skeleton.

Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency.

The authority application must be in writing and must include:

1. Details of the proposed prescription; **AND**
2. A completed Severe Growth Hormone Deficiency supporting information form; **AND**
3. Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device**

11495B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	386.83	31.60	Genotropin GoQuick [PF]

**somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device**

11493X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	166.24	31.60	Genotropin GoQuick [PF]

**somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge**

13709M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	386.83	31.60	Saizen [SG]

**somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge**

11895C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	166.24	31.60	Norditropin FlexPro [NO]

**somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge**

13712Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	197.75	31.60	Saizen [SG]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Short stature and slow growth



Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex, **AND**
- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); **OR**
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; **OR**
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Confirmation of the patient's maturational or constitutional delay status; **AND**
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1<sup>st</sup> adult height percentile; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test

(pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels;  
OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary

stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1st percentile for age and sex; AND
4. A bone age result performed within the last 12 months; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone

stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Confirmation that the patient has precocious puberty; **AND**
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); **OR**
- Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; **OR**  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
8. Confirmation that the patient has hypothalamic obesity; **AND**
9. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex, **AND**
- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR

(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; AND

4. A bone age result performed within the last 12 months; AND

5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> ; AND

6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10514J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	333.90	31.60	Omnitrope Surepal 10 [SZ]

### somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

6311E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	333.90	31.60	SciTropin A [SA]

### somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10446T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	496.51	31.60	Omnitrope Surepal 15 [SZ]

### somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10518N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	171.28	31.60	Omnitrope Surepal 5 [SZ]

### somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

6476W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	171.28	31.60	Scitropin A [SA]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Short stature and slow growth

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex, **AND**
- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR



- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation of the patient's maturational or constitutional delay status; AND
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1<sup>st</sup> adult height percentile; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

## **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

## **Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

## **AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have an annual growth velocity of greater than 14 cm per year if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

## **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex, **AND**
- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

#### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

#### **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

#### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

#### **Clinical criteria:**

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **OR**  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> ; **AND**
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge**

5824M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	386.83	31.60	Saizen [SG]

**somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge**

3388H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	659.14	31.60	Saizen [SG]

**somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge**

5822K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	197.75	31.60	Saizen [SG]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos). Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Short stature and slow growth  
Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex, **AND**
- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); **OR**
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**



- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

#### Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
  - Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
  - Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.
- An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Confirmation of the patient's maturational or constitutional delay status; **AND**
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1<sup>st</sup> adult height percentile; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

#### Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

#### Clinical criteria:

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR

- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
  - Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
  - Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.
- An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR
- (b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have an annual growth velocity of greater than 14 cm per year if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

### **Clinical criteria:**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex, **AND**
- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> ; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge**

5819G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	333.90	31.60	Norditropin FlexPro [NO]

**somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge**

5820H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	496.51	31.60	Norditropin FlexPro [NO]

**somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge**

5818F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	166.24	31.60	Norditropin FlexPro [NO]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Short stature and slow growth  
Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex, **AND**



- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 160.1 cm; OR
- Patient must be female and must not have maturational or constitutional delay in combination with an estimated mature height equal to or above 148.0 cm.

#### Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Confirmation of the patient's maturational or constitutional delay status; **AND**
6. If the patient has maturational or constitutional delay, confirmation that the patient has an estimated mature height below the 1<sup>st</sup> adult height percentile; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

#### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Initial treatment

#### **Clinical criteria:**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test

(pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary

stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and a growth velocity below the 25th percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have a current height above the 1<sup>st</sup> percentile for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
5. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; **OR**
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; **OR**
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (males chronological age 12 and over or bone age 10 and over, females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Confirmation that the patient has precocious puberty; AND
7. Confirmation that the patient is undergoing Gonadotropin Releasing Hormone agonist therapy, for pubertal suppression; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have a structural lesion that is not neoplastic; OR
  - Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
  - Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,
- AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
  - Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
  - Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
  - Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
  - Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
  - Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
  - Patient must have hypothalamic obesity, **AND**
  - Patient must have a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
  - Patient must have an annual growth velocity of greater than 14 cm per year if the patient has a chronological age of 2 years or less; OR
  - Patient must have an annual growth velocity of greater than 8 cm per year if the patient has a bone or chronological age of 2.5 years or less, **AND**
  - Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
  - Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
  - Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
  - Patient must be male and must not have a bone age of 15.5 years or more; OR
  - Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
7. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
8. Confirmation that the patient has hypothalamic obesity; AND
9. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Testing for biochemical growth hormone deficiency must have been performed at a time when all other pituitary hormone deficits were being adequately replaced.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Initial treatment

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

**Clinical criteria:**

- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must not have a height greater than or equal to 155.0cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. (a) A minimum of 12 months of recent growth data (height and weight) at intervals no greater than six months. The most recent data must not be older than three months; OR  
(b) A minimum of 6 months of recent growth data (height and weight) for older children (females chronological age 10 and over or bone age 8 and over). The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex, **AND**
- Patient must have a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
6. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Initial treatment

### **Clinical criteria:**

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR

- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must have a current height at or below the 1<sup>st</sup> percentile for age and sex; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over a 12 month interval (or a 6 month interval for an older child); OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 14 cm per year or less if the patient has a chronological age of 2 years or less; OR
- Patient must have a current height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex and an annual growth velocity of 8 cm per year or less if the patient has a bone or chronological age of 2.5 years or less, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; **AND**
3. (a) A minimum of 12 months of recent growth data (height and weight measurements) or a minimum of 6 months of recent growth data for an older child. The most recent data must not be more than three months old at the time of application; OR  
(b) Height and weight measurements, not more than three months old at the time of application, for a patient whose current height is at or below the 1<sup>st</sup> percentile for age and sex; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> ; **AND**
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Initial treatment

**Clinical criteria:**

- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have previously received treatment under the PBS S100 Growth Hormone Program, **AND**



## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must not have a chronological age of 18 years or greater.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.

The maximum duration of the initial treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for initial treatment; AND
3. A minimum of 6 months of recent growth data (height, weight and waist circumference). The most recent data must not be older than three months; AND
4. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND
5. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome; OR  
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist
6. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months and any sleep disorders identified via polysomnography that required treatment have been addressed; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with 1 repeat allowed)

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**somatropin 400 microgram injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10902T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	100.23	31.60	Genotropin MiniQuick [PF]

**somatropin 600 microgram injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

9628R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	145.27	31.60	Genotropin MiniQuick [PF]

**somatropin 800 microgram injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

6313G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	190.81	31.60	Genotropin MiniQuick [PF]

**somatropin 1 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

6314H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	236.34	31.60	Genotropin MiniQuick [PF]

**somatropin 1.2 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

6315J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	281.87	31.60	Genotropin MiniQuick [PF]

**somatropin 1.4 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

6316K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	327.40	31.60	Genotropin MiniQuick [PF]

**somatropin 1.6 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

6317L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	372.93	31.60	Genotropin MiniQuick [PF]

**somatropin 1.8 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

6318M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	418.46	31.60	Genotropin MiniQuick [PF]

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### somatropin 2 mg injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

6319N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	463.99	31.60	Genotropin MiniQuick [PF]

### somatropin 12 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device

9586M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	386.83	31.60	Genotropin GoQuick [PF]

### somatropin 5 mg injection [1 chamber] (&) inert substance diluent [1 mL chamber], 1 dual chamber pen device

9585L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	166.24	31.60	Genotropin GoQuick [PF]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).  
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)  
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.  
The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**

3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**

• Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

### Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### Authority required

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

### Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months; AND

5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

## **Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## Authority required

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR



- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

#### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

#### Population criteria:

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months; **AND**
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; **AND**
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

#### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both: (i) a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years,

**AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR  
(b) Confirmation that the patient has previously received treatment under the indication short stature associated with chronic renal insufficiency, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND
4. Recent growth data (height and weight, not older than three months); AND
5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
6. The proprietary name (brand), form and strength of the growth hormone requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of

- growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
  - Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
  - Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
  - Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
  - Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
  - Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
  - Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
  - Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
  - Patient must be male and must not have a bone age of 15.5 years or more; OR
  - Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; **OR**
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Recent growth data (height and weight, not older than three months); **AND**
9. A bone age result performed within the last 12 months; **AND**
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR



- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

#### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

#### **Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

#### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR

(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND

4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND

5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10481P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	333.90	31.60	SciTropin A [SA]

### somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10519P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	333.90	31.60	Omnitrope Surepal 10 [SZ]

### somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10485W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	496.51	31.60	Omnitrope Surepal 15 [SZ]

### somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10484T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	171.28	31.60	Scitropin A [SA]

### somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10512G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	171.28	31.60	Omnitrope Surepal 5 [SZ]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos).

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

### Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR



- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both: (i) a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years,

## **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR  
(b) Confirmation that the patient has previously received treatment under the indication short stature associated with chronic renal insufficiency, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND
4. Recent growth data (height and weight, not older than three months); AND
5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
6. The proprietary name (brand), form and strength of the growth hormone requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

#### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

#### **Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**

- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**



- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of

- growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
  - Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
  - Patient must have a structural lesion that is not neoplastic; OR
  - Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
  - Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**
7. Confirmation that the patient has hypothalamic obesity; **AND**
8. Recent growth data (height and weight, not older than three months); **AND**
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
  6. Recent growth data (height and weight, not older than three months); AND
  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
- In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months; AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

## **Population criteria:**

- Patient must be aged 3 years or older.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge

10495J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	386.83	31.60	Saizen [SG]

### somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge

10442N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	659.14	31.60	Saizen [SG]

### somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge

10458K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	197.75	31.60	Saizen [SG]

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR



- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If commencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If commencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### Authority required

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

### Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; **AND**
3. Recent growth data (height and weight, not older than three months); **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND

2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both: (i) a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years,

## **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR  
(b) Confirmation that the patient has previously received treatment under the indication short stature associated with chronic renal insufficiency, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND
4. Recent growth data (height and weight, not older than three months); AND
5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
6. The proprietary name (brand), form and strength of the growth hormone requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**



- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone

stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; **AND**
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; **AND**

7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient



was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND

4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND

5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND

6. Recent growth data (height and weight, not older than three months); AND

7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

### somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10496K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	333.90	31.60	Norditropin FlexPro [NO]

### somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10489C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	496.51	31.60	Norditropin FlexPro [NO]

### somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10467X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	166.24	31.60	Norditropin FlexPro [NO]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### **Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**

- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

#### **Treatment criteria:**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

#### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months; **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months; AND



5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

## **Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both: (i) a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years,

## **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR

(b) Confirmation that the patient has previously received treatment under the indication **short stature associated with chronic renal insufficiency**, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND

4. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline

abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

#### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months; AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

#### **Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant);  
OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND

3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR

(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND

5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR

(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

7. A bone age result performed within the last 12 months; AND

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months; **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR

- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; **OR**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); **OR**
- Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; **OR**
- Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

### Population criteria:

- Patient must be aged 3 years or older.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; **OR**  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); **OR**

(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND

6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND

7. Confirmation that the patient has hypothalamic obesity; AND

8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

9. A bone age result performed within the last 12 months; AND

10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or commencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND



5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Population criteria:**

- Patient must be aged 3 years or older.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special**

**Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup> ; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature and slow growth

Treatment Phase: Change of drug

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

**Clinical criteria:**

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR

- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

Definition:

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.

2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.

Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 13 weeks of treatment per dispensing. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 26 weeks of treatment.

An online calculator has been developed to assist in the determination of the quantity of drug to be sought. It is located in the following location:

<https://www.pbs.gov.au/browse/section100-gh>

#### **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Change of drug

#### **Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

#### **Clinical criteria:**

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

#### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

Definition:

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.

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2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 13 weeks of treatment per dispensing. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 26 weeks of treatment.

An online calculator has been developed to assist in the determination of the quantity of drug to be sought. It is located in the following location:

<https://www.pbs.gov.au/browse/section100-gh>

### somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10441M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	333.90	31.60	SciTropin A [SA]

### somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10506Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	333.90	31.60	Omnitrope Surepal 10 [SZ]

### somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10490D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	496.51	31.60	Omnitrope Surepal 15 [SZ]

### somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10427T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	171.28	31.60	Scitropin A [SA]

### somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10507B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	171.28	31.60	Omnitrope Surepal 5 [SZ]

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au). Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos).

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR

- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND

4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment

**Clinical criteria:**



- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height and weight, not older than three months); AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup>; AND
6. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND

7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

If a patient receiving treatment under the indication 'short stature associated with chronic renal insufficiency' undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

## **Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader Willi syndrome category, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems; OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by a significant medical illness; OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and treatment must not have lapsed due to failure to respond to growth hormone at a dose of 0.04mg/kg/wk or greater for the most recent treatment period (32 weeks for the initial treatment period or 26 weeks for subsequent treatment periods, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

**Population criteria:**

- Patient must not have a chronological age of equal to or greater than 18 years.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment; AND
3. Recent growth data (height, weight, and waist circumference, not older than three months); AND
4. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity.]; AND
5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; AND
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If recommencement of treatment is sought under a different indication than that under which the patient was previously receiving treatment an application for **recommencement of treatment as a reclassified patient** should be submitted.

**Authority required**

Short stature and slow growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both: (i) a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years,

**AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

#### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR  
(b) Confirmation that the patient has previously received treatment under the indication short stature associated with chronic renal insufficiency, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND
4. Recent growth data (height and weight, not older than three months); AND
5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
6. The proprietary name (brand), form and strength of the growth hormone requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

#### Authority required

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR

- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants and has reached or surpassed 5 years of age (chronological); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. Recent growth data (height and weight, not older than three months); **AND**



6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25th percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR

- Patient must have had both a height above the 1st percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Recent growth data (height and weight, not older than three months); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone

stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

### **AND**

- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient

was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Recent growth data (height and weight, not older than three months); AND
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must not have a bone age of 13.5 years or greater.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program)**

**Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Recent growth data (height and weight, not older than three months); AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Recent growth data (height and weight, not older than three months); AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Recommencement of treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency, **AND**
- Patient must have had a lapse in treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR



- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1st percentile for age and sex immediately prior to commencing treatment; **AND**
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> ; **AND**
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
6. Recent growth data (height and weight, not older than three months); **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Recommencement of treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, **AND**
- Patient must have had a lapse in growth hormone treatment, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

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- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with no sleep disorders identified; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified which are not of sufficient severity to require treatment; OR
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea within the last 12 months with sleep disorders identified for which the patient is currently receiving ameliorative treatment, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height,

### AND

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 18 years or greater.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each recommencement treatment phase is 32 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for recommencement of treatment as a reclassified patient; AND
3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR  
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; AND
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment or within the last 12 months, and any sleep disorders identified via the polysomnography that required treatment have been addressed; AND
5. Recent growth data (height and weight, not older than three months); AND
6. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 16 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### somatropin 400 microgram injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10908D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	100.23	31.60	Genotropin MiniQuick [PF]

### somatropin 600 microgram injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10477K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	145.27	31.60	Genotropin MiniQuick [PF]

### somatropin 800 microgram injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10463Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	190.81	31.60	Genotropin MiniQuick [PF]

**somatropin 1 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10430Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	236.34	31.60	Genotropin MiniQuick [PF]

**somatropin 1.2 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10457J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	281.87	31.60	Genotropin MiniQuick [PF]

**somatropin 1.4 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10434E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	327.40	31.60	Genotropin MiniQuick [PF]

**somatropin 1.6 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10498M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	372.93	31.60	Genotropin MiniQuick [PF]

**somatropin 1.8 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10501Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	418.46	31.60	Genotropin MiniQuick [PF]

**somatropin 2 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10472E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	463.99	31.60	Genotropin MiniQuick [PF]

**somatropin 12 mg injection [1 chamber] (& inert substance diluent [1 mL chamber], 1 dual chamber pen device**

10426R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	386.83	31.60	Genotropin GoQuick [PF]

**somatropin 5 mg injection [1 chamber] (& inert substance diluent [1 mL chamber], 1 dual chamber pen device**

10435F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	166.24	31.60	Genotropin GoQuick [PF]

▪ **SOMATROPIN**

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au) Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos) Or mailed to:  
Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND

6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

5. The final adult height (in cm) of the patient's mother and father (where available); AND  
 6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND



5. The final adult height (in cm) of the patient's mother and father (where available); AND  
 6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both: (i) a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years,

**AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR  
(b) Confirmation that the patient has previously received treatment under the indication **short stature associated with chronic renal insufficiency**, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; AND
4. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

## **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

#### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**

6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion,

**AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR



- Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); **OR**
- Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; **OR**
- Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; **OR**
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; **OR**
- Patient must be female and must not have a bone age of 13.5 years or more.

#### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; **OR**
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

#### Authority required

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

#### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup> ; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

## **Authority required**

Short stature and slow growth

Treatment Phase: Change of drug

## **Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

## **Clinical criteria:**

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

## **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

## **Definition:**

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 13 weeks of treatment per dispensing. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 26 weeks of treatment.

An online calculator has been developed to assist in the determination of the quantity of drug to be sought. It is located in the following location:

<https://www.pbs.gov.au/browse/section100-gh>

## **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Change of drug

## **Treatment criteria:**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

### Clinical criteria:

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

### Definition:

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.

Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 13 weeks of treatment per dispensing. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 26 weeks of treatment.

An online calculator has been developed to assist in the determination of the quantity of drug to be sought. It is located in the following location:

<https://www.pbs.gov.au/browse/section100-gh>

### somatropin 10 mg/1.5 mL injection, 1.5 mL cartridge

10451C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	333.90	31.60	Norditropin FlexPro [NO]

### somatropin 15 mg/1.5 mL injection, 1.5 mL cartridge

10449Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	496.51	31.60	Norditropin FlexPro [NO]

### somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge

10432C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	166.24	31.60	Norditropin FlexPro [NO]

## ▪ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online

Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)  
 Or mailed to:  
 Services Australia  
 Complex Drugs  
 Reply Paid 9826  
 HOBART TAS 7001

## **Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Treatment criteria:**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

## **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**



3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both: (i) a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a

growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years, **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); **OR**  
(b) Confirmation that the patient has previously received treatment under the indication **short stature associated with chronic renal insufficiency**, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; **AND**
4. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; **OR**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR
  - (b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
  - (c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**

5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-3 levels, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR

- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR



- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; AND
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone

stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. Confirmation that the patient has precocious puberty; AND
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; AND
5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**
- Patient must have had a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient

was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND

4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A height measurement from immediately prior to commencement of growth hormone treatment; AND
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; AND
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; AND
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Population criteria:**

- Patient must be aged 3 years or older.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND

4. A bone age result performed within the last 12 months; AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

## **Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

## **Population criteria:**

- Patient must be aged 3 years or older.

## **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; AND
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup>; AND
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; AND
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
7. A bone age result performed within the last 12 months; AND

The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

## **Authority required**

Short stature and slow growth

Treatment Phase: Change of drug

### **Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

### **Clinical criteria:**

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

Definition:

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.



Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 13 weeks of treatment per dispensing. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 26 weeks of treatment.

An online calculator has been developed to assist in the determination of the quantity of drug to be sought. It is located in the following location:

<https://www.pbs.gov.au/browse/section100-gh>

## **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Change of drug

### **Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

### **Clinical criteria:**

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### **Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

### **Definition:**

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 13 weeks of treatment per dispensing. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 26 weeks of treatment.

An online calculator has been developed to assist in the determination of the quantity of drug to be sought. It is located in the following location:

<https://www.pbs.gov.au/browse/section100-gh>

### somatropin 12 mg/1.5 mL injection, 1.5 mL cartridge

10483R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	386.83	31.60	Saizen [SG]

### somatropin 20 mg/2.5 mL injection, 2.5 mL cartridge

10497L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	659.14	31.60	Saizen [SG]

### somatropin 6 mg/1.03 mL injection, 1.03 mL cartridge

10462P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	197.75	31.60	Saizen [SG]

## ■ SOMATROPIN

**Note** Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at [www.servicesaustralia.gov.au](http://www.servicesaustralia.gov.au)

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at [www.servicesaustralia.gov.au/hpos](http://www.servicesaustralia.gov.au/hpos)

Or mailed to:

Services Australia  
Complex Drugs  
Reply Paid 9826  
HOBART TAS 7001

### Authority required

Short stature and slow growth

Treatment Phase: Continuing treatment

### Clinical criteria:

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and slow growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

### Treatment criteria:

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with biochemical growth hormone deficiency category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the growth retardation secondary to an intracranial lesion, or cranial irradiation category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

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- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

### **Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 5 years or greater.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND

3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

When a patient receiving treatment under the indication risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants reaches or surpasses 5 years of age (chronological), prescribers should seek reclassification to the indication 'short stature due to biochemical growth hormone deficiency'.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the biochemical growth hormone deficiency and precocious puberty category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth category, **AND**
- Patient must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with Turner syndrome category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an annualised growth velocity for bone age at or above the mean growth velocity for untreated Turner Syndrome girls (using the Turner Syndrome - Ranke growth velocity chart) while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**

2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature due to short stature homeobox (SHOX) gene disorders category, **AND**
- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; AND
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
5. The final adult height (in cm) of the patient's mother and father (where available); AND
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature associated with chronic renal insufficiency category, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**

- Patient must not have been on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved the 50th percentile growth velocity for bone age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved an increase in height standard deviation score for chronological age and sex while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved a minimum growth velocity of 4cm/year while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have achieved and maintained mid parental height standard deviation score while on the maximum dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have undergone a renal transplant within the 12 month period immediately prior to the date of application, **AND**
- Patient must not have an eGFR equal to or greater than 30mL/min/1.73m<sup>2</sup>, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7 cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0 cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
5. The final adult height (in cm) of the patient's mother and father (where available); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

**Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under the short stature and poor body composition due to Prader-Willi syndrome category, **AND**
- Patient must have been re-evaluated via polysomnography for airway obstruction and apnoea during the initial 32 week treatment period and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must not have been on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved height percentile for age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved waist circumference while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment



period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age below skeletal maturity (15.5 years for males and 13.5 years for females) (except where the patient had a chronological age of 2.5 years or less) at the last application and must have achieved an increase in height percentile with reference to the untreated Prader-Willi syndrome standards for age and sex while on the maximum dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must not have been on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved body mass index while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved body mass index SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved waist circumference while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved waist/height ratio (waist circumference in centimetres divided by height in centimetres) while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- Patient must have had a bone age at or above skeletal maturity (15.5 years for males and 13.5 years for females) at the last application and must have maintained or improved weight SDS for age and sex while on the maximum dose of 0.04mg/kg/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have developed uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height.

**Population criteria:**

- Patient must not have a chronological age of equal to or greater than 18 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment; **AND**
3. Growth data (height, weight and waist circumference) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
4. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; **AND**
5. Confirmation that during the initial 32 week treatment period, the patient was re-evaluated via polysomnography for airway obstruction and apnoea, and any sleep disorders that were identified have been addressed; **AND**
6. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Maintenance is defined as a value within a 5% tolerance (this allows for seasonal and other measurement variations).

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature and slow growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature and slow growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication short stature associated with chronic renal insufficiency, have undergone a renal transplant and a 12 month period of observation following the transplant, and have an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both: (i) a height no higher than the 1<sup>st</sup> percentile for age plus sex at the time of having commenced treatment with this drug, (ii) over the 12 month interval immediately prior to having commenced treatment, a growth velocity no greater than 8 cm/year where the patient had a bone/chronological age of no greater than 2.5 years,

**AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (where the patient's chronological age was higher than 2.5 years); OR  
(b) Confirmation that the patient has previously received treatment under the indication **short stature associated with chronic renal insufficiency**, has undergone a renal transplant and a 12 month period of observation following the transplant, and has an estimated glomerular filtration rate of greater than or equal to 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula; **AND**
4. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
5. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

## **Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Continuing treatment as a reclassified patient

## **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with biochemical growth hormone deficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and have reached or surpassed 5 years of age (chronological); OR
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**

- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics, **AND**

• Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time. An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR  
(c) Confirmation that the patient has previously received treatment under the indication **risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants** and has reached or surpassed 5 years of age (chronological); **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

Biochemical growth hormone deficiency should not be secondary to an intracranial lesion or cranial irradiation for applications under this category.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Growth retardation secondary to an intracranial lesion, or cranial irradiation

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than growth retardation secondary to an intracranial lesion, or cranial irradiation, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had an intracranial lesion which is under appropriate observation and management; OR
- Patient must have received cranial irradiation without having had an intracranial lesion, and is under appropriate observation and management, **AND**

- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; **AND**
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; **AND**
5. (a) Confirmation that the patient has had an intracranial lesion which is under appropriate observation and management; OR  
(b) Confirmation that the patient has received cranial irradiation without having had an intracranial lesion and is under appropriate observation and management; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**

8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a chronological age of less than 2 years, **AND**
- Patient must have a documented clinical risk of hypoglycaemia, **AND**
- Patient must have documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has a documented clinical risk of hypoglycaemia; **AND**
4. Confirmation that the patient has documented evidence that the risk of hypoglycaemia is secondary to biochemical growth hormone deficiency; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Biochemical growth hormone deficiency and precocious puberty

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than biochemical growth hormone deficiency and precocious puberty, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must be male and have commenced puberty (demonstrated by Tanner stage 2 genital or pubic hair development or testicular volumes greater than or equal to 4 mL) before the chronological age of 9 years; OR
- Patient must be female and have commenced puberty (demonstrated by Tanner stage 2 breast or pubic hair development) before the chronological age of 8 years; OR
- Patient must be female and menarche occurred before the chronological age of 10 years, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must be undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

#### Treatment criteria:

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. Confirmation that the patient has precocious puberty; **AND**
4. Confirmation that the patient is undergoing Gonadotrophin Releasing Hormone agonist therapy for pubertal suppression; **AND**

5. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
  6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
  7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
  8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).
- Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.
- In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have a structural lesion that is not neoplastic; OR
- Patient must have had a structural lesion that was neoplastic and have undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR
- Patient must have a structural lesion that is neoplastic, have received medical advice that it is unsafe to treat the structural lesion, and have undergone a 12 month period of observation since initial diagnosis of the structural lesion, **AND**
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 2 pharmacological growth hormone stimulation tests (e.g. arginine, clonidine, glucagon, insulin); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 pharmacological growth hormone stimulation test (e.g. arginine, clonidine, glucagon, insulin) and 1 physiological growth hormone stimulation test (e.g. sleep, exercise); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) with other evidence of growth hormone deficiency, including septo-optic dysplasia (absent corpus callosum and/or septum pellucidum), midline abnormality including optic nerve hypoplasia, cleft lip and palate, midfacial hypoplasia and central incisor, ectopic and/or absent posterior pituitary bright spot, absent empty sella syndrome, hypoplastic anterior pituitary gland and/or pituitary stalk/infundibulum, and genetically proven biochemical growth hormone deficiency either isolated or as part of hypopituitarism in association with pituitary deficits (ACTH, TSH, GnRH or vasopressin/ADH deficiency); OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGF-1 levels; OR
- Patient must have evidence of biochemical growth hormone deficiency, with a peak serum growth hormone concentration less than 10 mU/L or less than or equal to 3.3 micrograms per litre in response to 1 growth hormone stimulation test (pharmacological or physiological e.g. arginine, clonidine, glucagon, insulin, sleep, exercise) and low plasma IGFBP-3 levels, **AND**
- Patient must have other hypothalamic/pituitary hormone deficits (includes ACTH, TSH, GnRH and/or vasopressin/ADH deficiencies), **AND**
- Patient must have hypothalamic obesity, **AND**



- Patient must have had a growth velocity above the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of greater than 14 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of greater than 8 cm per year in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; AND
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; AND
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); AND
4. Evidence of biochemical growth hormone deficiency, including the type of tests performed and peak growth hormone concentrations; AND
5. (a) Confirmation that the patient has a structural lesion that is not neoplastic; OR  
(b) Confirmation that the patient had a structural lesion that was neoplastic and has undergone a 12 month period of observation following completion of treatment for the structural lesion (all treatment); OR  
(c) Confirmation that the patient has a structural lesion that is neoplastic, has received medical advice that it is unsafe to treat the structural lesion, and has undergone a 12 month period of observation since initial diagnosis of the structural lesion; AND
6. Confirmation that the patient has other hypothalamic/pituitary hormone deficits; AND
7. Confirmation that the patient has hypothalamic obesity; AND
8. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; AND
9. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); AND
10. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with Turner syndrome

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature associated with Turner syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in all cells (45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as a loss of a whole X chromosome in some cells (mosaic 46XX/45X), and gender of rearing is female; OR
- Patient must have diagnostic results consistent with Turner syndrome (the condition must be genetically proven), defined as genetic loss or rearrangement of an X chromosome (such as isochromosome X, ring-chromosome, or partial deletion of an X chromosome), and gender of rearing is female, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a bone age of 13.5 years or greater, **AND**
- Patient must not have a height greater than or equal to 155.0 cm.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A height measurement from immediately prior to commencement of growth hormone treatment; **AND**
4. Confirmation that the patient has diagnostic results consistent with Turner syndrome; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
7. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature due to short stature homeobox (SHOX) gene disorders

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature due to short stature homeobox (SHOX) gene disorders, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a

continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**

- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as a karyotype confirming the presence of a SHOX mutation/deletion without the presence of mixed gonadal dysgenesis; OR
- Patient must have diagnostic results consistent with a SHOX mutation/deletion, defined as mixed gonadal dysgenesis (45X mosaic karyotype with the presence of any Y chromosome material and/or SRY gene positive by FISH study) and have an appropriate plan of management in place for the patient's increased risk of gonadoblastoma, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment, **AND**
- Patient must have had a growth velocity below the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes (excluding gonadoblastoma secondary to mixed gonadal dysgenesis), **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); **AND**
4. Confirmation that the patient has diagnostic results consistent with a short stature homeobox (SHOX) gene disorder; **AND**
5. If the patient's condition is secondary to mixed gonadal dysgenesis, confirmation that an appropriate plan of management for the patient's increased risk of gonadoblastoma is in place; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**
8. The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature associated with chronic renal insufficiency

Treatment Phase: Continuing treatment as a reclassified patient

**Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program (treatment) under a category other than short stature associated with chronic renal insufficiency, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR

- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 9.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have had a height at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and a growth velocity less than or equal to the 25<sup>th</sup> percentile for bone age and sex measured over the 12 month interval immediately prior to commencement of treatment (or the 6 month interval immediately prior to commencement of treatment if the patient was an older child at commencement of treatment); OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 14 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a chronological age of 2 years or less at commencement of treatment; OR
- Patient must have had both a height above the 1<sup>st</sup> and at or below the 25<sup>th</sup> percentiles for age and sex immediately prior to commencing treatment and an annual growth velocity of 8 cm per year or less in the 12 month period immediately prior to commencement of treatment, if the patient had a bone or chronological age of 2.5 years or less at commencement of treatment, **AND**
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, and not have undergone a renal transplant; OR
- Patient must have an estimated glomerular filtration rate less than 30mL/minute/1.73m<sup>2</sup> measured by creatinine clearance, excretion of radionuclides such as DTPA, or by the height/creatinine formula, have undergone a renal transplant, and have undergone a 12 month period of observation following the transplant, **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

**Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

An older child is defined as a male with a chronological age of at least 12 years or a bone age of at least 10 years, or a female with a chronological age of at least 10 years or a bone age of at least 8 years.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) A minimum of 12 months of growth data (height and weight measurements) from immediately prior to commencement of treatment, or a minimum of 6 months of growth data from immediately prior to commencement of treatment if the patient was an older child at commencement of treatment; and the result of a bone age assessment performed within the 12 months immediately prior to commencement of treatment (except for a patient whose chronological age was 2.5 years or less at commencement of treatment); OR  
(b) Height and weight measurements from within three months prior to commencement of treatment for a patient whose height was at or below the 1<sup>st</sup> percentile for age and sex immediately prior to commencing treatment; **AND**
4. Confirmation that the patient has an estimated glomerular filtration rate less than 30ml/minute/1.73m<sup>2</sup> ; **AND**
5. If a renal transplant has taken place, confirmation that the patient has undergone a 12 month period of observation following transplantation; **AND**
6. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
7. A bone age result performed within the last 12 months (except for a patient whose chronological age is 2.5 years or less); **AND**

The proprietary name (brand), form and strength of somatropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** If a patient receiving treatment under the indication short stature due to chronic renal insufficiency undergoes a renal transplant and 12 months post-transplant has an eGFR of equal to or greater than 30mL/min/1.73m<sup>2</sup> prescribers should seek reclassification to the indication short stature and slow growth.

## **Authority required**

Short stature and poor body composition due to Prader-Willi syndrome

Treatment Phase: Continuing treatment as a reclassified patient

### **Clinical criteria:**

- Patient must have previously received treatment under the PBS S100 Growth Hormone Program under a category other than short stature and poor body composition due to Prader-Willi syndrome, **AND**
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by a significant medical illness; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by major surgery (e.g. renal transplant); OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by an adverse reaction to growth hormone; OR
- The treatment must not have lapsed due to failure to respond to growth hormone at a dose of 7.5mg/m<sup>2</sup>/week or greater for the most recent treatment period (32 weeks for an initial or recommencement treatment period and 26 weeks for a continuing treatment period, whichever applies), unless response was affected by non-compliance due to social/family problems, **AND**
- Patient must have diagnostic results consistent with Prader-Willi syndrome (the condition must be genetically proven); OR
- Patient must have a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist, **AND**
- Patient must have been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment and any sleep disorders identified that required treatment must have been addressed, **AND**
- Patient must not have uncontrolled morbid obesity, defined as a body weight greater than 200% of ideal body weight for height and sex, with ideal body weight derived by calculating the 50th percentile weight for the patient's current height,

### **AND**

- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must not have a chronological age of 18 years or greater.

### **Treatment criteria:**

- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.

The maximum duration of each continuing treatment phase is 26 weeks. Prescribers must determine an appropriate weekly dose in accordance with the dosing arrangements detailed in the **National Health (Growth Hormone Program) Special Arrangement 2015** and request the appropriate number of vials/cartridges required to provide sufficient drug for 13 weeks' worth of treatment (with up to 1 repeat allowed).

The authority application must be in writing and must include:

1. A completed authority prescription form; **AND**
2. A completed Growth Hormone Authority Application Supporting Information Form for continuing treatment as a reclassified patient; **AND**
3. (a) Confirmation that the patient has diagnostic results consistent with Prader-Willi syndrome, OR  
(b) Confirmation that the patient has a clinical diagnosis of Prader-Willi syndrome, confirmed by a clinical geneticist; **AND**
4. Confirmation that the patient has been evaluated via polysomnography for airway obstruction and apnoea whilst on growth hormone treatment, and any sleep disorders identified via the polysomnography that required treatment have been addressed; **AND**
5. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months; **AND**
6. The date at which skeletal maturity was achieved (if applicable) [Note: In patients whose chronological age is greater than 2.5 years, a bone age reading should be performed at least once every 12 months prior to attainment of skeletal maturity]; **AND**

7. The proprietary name (brand), form and strength of somatotropin requested, and the number of vials/cartridges required to provide sufficient drug for 13 weeks worth of treatment (with up to 1 repeat allowed).

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Authority required**

Short stature and slow growth

Treatment Phase: Change of drug

**Treatment criteria:**

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

**Clinical criteria:**

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more, **AND**
- Patient must be male and must not have a height greater than or equal to 167.7cm; OR
- Patient must be female and must not have a height greater than or equal to 155.0cm.

**Treatment criteria:**

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

**Definition:**

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years. Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 13 weeks of treatment per dispensing. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 26 weeks of treatment.

An online calculator has been developed to assist in the determination of the quantity of drug to be sought. It is located in the following location:

<https://www.pbs.gov.au/browse/section100-gh>

**Authority required**

Short stature associated with biochemical growth hormone deficiency

Treatment Phase: Change of drug

**Treatment criteria:**

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

- Patient must be undergoing existing PBS-subsidised growth hormone treatment where the prescribed drug is changing within the same PBS indication - subsidy through this treatment phase must not: (i) initiate treatment, (ii) recommence treatment, (iii) reclassify the PBS indication.

### Clinical criteria:

- Patient must have been treated with PBS-subsidised growth hormone for less than 32 weeks; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) having been demonstrated; OR
- Patient must have been treated with PBS-subsidised growth hormone for at least 32 weeks, with an adequate response to treatment (as defined further below) not demonstrated due to at least one of: (i) a significant medical illness, (ii) major surgery (e.g. renal transplant), (iii) an adverse reaction to growth hormone, (iv) non-compliance to treatment arising from social/family problems, (v) sub-optimal dosing (i.e. the dose was less than the permitted upper dose range), **AND**
- Patient must not have a condition with a known risk of malignancy including chromosomal abnormalities such as Down and Bloom syndromes, **AND**
- Patient must not have an active tumour or evidence of tumour growth or activity, **AND**
- Patient must be male and must not have a bone age of 15.5 years or more; OR
- Patient must be female and must not have a bone age of 13.5 years or more.

### Treatment criteria:

- Must be treated by a specialist or consultant physician in paediatric endocrinology; OR
- Must be treated by a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology, **AND**
- Patient must be undergoing treatment for the stated indication with only one growth hormone at any given time.

### Definition:

An adequate response to the preceding supply of growth hormone for which the patient is changing from is one where the patient, for their sex, has achieved at least one of:

- (a) the 50<sup>th</sup> percentile growth velocity for bone age;
- (b) an increase in height standard deviation score for chronological age;
- (c) a minimum growth velocity of 4 cm per year;
- (d) a mid-parental height standard deviation score.

Applications for authorisation under this treatment phase must be made via the Online PBS Authorities System (real time assessment) or in writing via HPOS form upload or mail and must include:

1. Growth data (height and weight) for the most recent 6 month treatment period, including data at both the start and end of the treatment period. The most recent data must not be older than three months.
2. A bone age result performed within the last 12 months where the patient has a chronological age greater than 2.5 years.

Where growth data has been supplied within 3 months of this authority application, do not resupply this data.

If the application is submitted through HPOS form upload or mail, it must include:

- (i) A completed authority prescription form; and
- (ii) A completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).

Prescribe an appropriate amount of drug (maximum quantity in units) outlined within the 'Notes' section of this restriction.

Prescribers must keep a copy of any clinical records relating to the prescription, including such records required to demonstrate that the prescription was written in compliance with any relevant circumstances and/or purposes. These records must be kept for 2 years after the date the prescription to which the records relate is written.

In children with diabetes mellitus prescribers must ascertain that a growth failure is not due to poor diabetes control, diabetes control is adequate, and regular screening occurs for diabetes complications, particularly retinopathy.

**Note** Prescribe an appropriate amount of drug (maximum quantity in units) that facilitates approximately 13 weeks of treatment per dispensing. Request up to 1 repeat prescription. With 1 repeat prescription, this treatment phase listing intends to provide approximately 26 weeks of treatment.

An online calculator has been developed to assist in the determination of the quantity of drug to be sought. It is located in the following location:

<https://www.pbs.gov.au/browse/section100-gh>

### somatropin 400 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10891F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	100.23	31.60	Genotropin MiniQuick [PF]

### somatropin 600 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10456H	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	145.27	31.60	Genotropin MiniQuick [PF]

### somatropin 800 microgram injection [1 chamber] (&) inert substance diluent [0.25 mL chamber], 7 dual chamber syringes

10479M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	190.81	31.60	Genotropin MiniQuick [PF]

SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

**somatropin 1 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10480N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	236.34	31.60	Genotropin MiniQuick [PF]

**somatropin 1.2 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10453E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	281.87	31.60	Genotropin MiniQuick [PF]

**somatropin 1.4 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10488B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	327.40	31.60	Genotropin MiniQuick [PF]

**somatropin 1.6 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10454F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	372.93	31.60	Genotropin MiniQuick [PF]

**somatropin 1.8 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10500P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	418.46	31.60	Genotropin MiniQuick [PF]

**somatropin 2 mg injection [1 chamber] (& inert substance diluent [0.25 mL chamber], 7 dual chamber syringes**

10428W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	463.99	31.60	Genotropin MiniQuick [PF]

**somatropin 12 mg injection [1 chamber] (& inert substance diluent [1 mL chamber], 1 dual chamber pen device**

10431B	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	386.83	31.60	Genotropin GoQuick [PF]

**somatropin 5 mg injection [1 chamber] (& inert substance diluent [1 mL chamber], 1 dual chamber pen device**

10443P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	166.24	31.60	Genotropin GoQuick [PF]



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# IVF Treatment Program

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## GENITO URINARY SYSTEM AND SEX HORMONES

### GENITO URINARY SYSTEM AND SEX HORMONES

### SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM

#### PROGESTOGENS

##### *Pregnen (4) derivatives*

#### PROGESTERONE

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

##### **Authority required (STREAMLINED)**

**4997**

Assisted Reproductive Technology

##### **Clinical criteria:**

- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, **AND**
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

##### **progesterone 100 mg pessary, 15**

9608Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*158.07	31.60	Oripro [ON]

##### **progesterone 200 mg pessary, 15**

9609R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*119.13	31.60	Oripro [ON]

##### **progesterone 100 mg pessary, 21**

10116K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*75.09	31.60	Endometrin [FP]

##### **progesterone 200 mg pessary, 42**

10930G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	88.20	31.60	Utrogestan [HB]

#### PROGESTERONE

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

**Note** Special Pricing Arrangements apply.

##### **Authority required (STREAMLINED)**

**5045**

Assisted Reproductive Technology

##### **Clinical criteria:**

- The treatment must be for luteal phase support as part of an assisted reproductive technology (ART) treatment cycle for infertile women, **AND**
- Patient must be receiving medical services as described in items 13200 or 13201 of the Medicare Benefits Schedule. The luteal phase is defined as the time span from embryo transfer until implantation confirmed by positive B-hCG measurement.

##### **progesterone 8% vaginal gel, 15 applications**

6366C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*203.81	31.60	Crinone 8% [SG]

## GONADOTROPINS AND OTHER OVULATION STIMULANTS

### *Gonadotropins*

#### CHORIOGONADOTROPIN ALFA

**Note** Pharmaceutical benefits that have the form choriogonadotropin alfa solution for injection 250 micrograms in 0.5 mL pre-filled syringe (Ovidrel USA) can be substituted for choriogonadotropin alfa solution for injection 250 micrograms in 0.5 mL pre-filled pen in the case of a shortage.

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

##### **Authority required (STREAMLINED)**

**14124**

Assisted Reproductive Technology

##### **Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

##### **Treatment criteria:**

- Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing.

**choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL syringe**

14656J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	125.98	31.60	<sup>a</sup> Ovidrel (USA) [SG]

▪ **CHORIOGONADOTROPIN ALFA**

**Note** Pharmaceutical benefits that have the form choriogonadotropin alfa solution for injection 250 micrograms in 0.5 mL pre-filled syringe (Ovidrel USA) can be substituted for choriogonadotropin alfa solution for injection 250 micrograms in 0.5 mL pre-filled pen in the case of a shortage.

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

**Note** Special Pricing Arrangements apply.

**Authority required (STREAMLINED)**

**14124**

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**Treatment criteria:**

- Patient must not be undergoing simultaneous treatment with this drug through another PBS program listing.

**choriogonadotropin alfa 250 microgram/0.5 mL injection, 0.5 mL pen device**

6182J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	78.26	31.60	<sup>a</sup> Ovidrel [SG]

▪ **CORIFOLLITROPIN ALFA**

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

**Authority required (STREAMLINED)**

**5009**

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for controlled ovarian stimulation, **AND**
- Patient must have an antral follicle count of 20 or less, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, or 13202 of the Medicare Benefits Schedule, **AND**
- Patient must be undergoing a gonadotrophin releasing antagonist cycle.

**corifollitropin alfa 100 microgram/0.5 mL injection, 0.5 mL syringe**

5816D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	393.63	31.60	Elonva [OQ]

**corifollitropin alfa 150 microgram/0.5 mL injection, 0.5 mL syringe**

5817E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	640.82	31.60	Elonva [OQ]

▪ **FOLLITROPIN ALFA**

**Note Biosimilar prescribing policy**

Prescribing of a biosimilar brand, Bemfola or Ovaleap, is encouraged for treatment naive patients.

**Note** Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ([www.health.gov.au/health-topics/medicines](http://www.health.gov.au/health-topics/medicines)).

**Note** Pharmaceutical benefits that have the form follitropin alfa cartridge (Ovaleap) and pharmaceutical benefits that have the form follitropin alfa single pen device (Gonal-f Pen), in the same corresponding strength, are equivalent for the purposes of substitution.

Where the Ovaleap brand is supplied, the separate pen device is to be supplied to the patient where required as it is not packaged with the cartridges. The pen device for the Ovaleap brand can be obtained by contacting the pharmaceutical wholesaler, or, the sponsor directly.

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

**Authority required (STREAMLINED)**

**5027**

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**follitropin alfa 300 units (21.84 microgram)/0.48 mL injection, 0.48 mL pen device**

6431L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*188.43	31.60	<sup>a</sup> Gonal-f Pen [SG]

## GENITO URINARY SYSTEM AND SEX HORMONES

### follitropin alfa 225 units (16.5 microgram)/0.375 mL injection, 5 x 0.375 mL pen devices

10872F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*969.21	31.60	Bemfola [FX]

### follitropin alfa 450 units (32.76 microgram)/0.72 mL injection, 0.72 mL pen device

6432M	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*278.31	31.60	<sup>a</sup> Gonal-f Pen [SG]

### follitropin alfa 900 units (65.52 microgram)/1.44 mL injection, 1.44 mL pen device

6433N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1686.07	31.60	<sup>a</sup> Gonal-f Pen [SG]

### follitropin alfa 450 units (33 microgram)/0.75 mL injection, 5 x 0.75 mL pen devices

10867Y	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*1895.88	31.60	Bemfola [FX]

### follitropin alfa 75 units (5.5 microgram)/0.125 mL injection, 5 x 0.125 mL pen devices

10861P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*328.83	31.60	Bemfola [FX]

### follitropin alfa 150 units (11 microgram)/0.25 mL injection, 5 x 0.25 mL pen devices

10873G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*649.05	31.60	Bemfola [FX]

### follitropin alfa 300 units (22 microgram)/0.5 mL injection, 5 x 0.5 mL pen devices

10866X	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*1280.16	31.60	Bemfola [FX]

### follitropin alfa 300 units (22 microgram)/0.5 mL injection, 0.5 mL cartridge

12779N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*188.43	31.60	<sup>a</sup> Ovaleap [TT]

### follitropin alfa 450 units (33 microgram)/0.75 mL injection, 0.75 mL cartridge

12800Q	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*278.31	31.60	<sup>a</sup> Ovaleap [TT]

### follitropin alfa 900 units (66 microgram)/1.5 mL injection, 1.5 mL cartridge

12770D	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1686.07	31.60	<sup>a</sup> Ovaleap [TT]

## ▪ FOLLITROPIN ALFA + LUTROPIN ALFA

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

#### **Authority required (STREAMLINED)**

**16362**

Stimulation of follicular development

#### **Clinical criteria:**

- Patient must have severe LH deficiency, **AND**
- Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### follitropin alfa 900 units (65.52 microgram)/1.44 mL + lutropin alfa 450 units/1.44 mL injection, 1.44 mL pen device

11667C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*3598.91	31.60	Pergoveris [SG]

## ▪ FOLLITROPIN BETA

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

#### **Authority required (STREAMLINED)**

**5027**

Assisted Reproductive Technology

#### **Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### follitropin beta 300 units/0.36 mL injection, 0.36 mL cartridge

6335K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*198.75	31.60	<sup>a</sup> Puregon 300 IU/0.36 mL [OQ]	<sup>a</sup> Recagon [OV]

**follitropin beta 600 units/0.72 mL injection, 0.72 mL cartridge**

6336L	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*750.47	31.60	Puregon 600 IU/0.72 mL [OQ]

**follitropin beta 900 units/1.08 mL injection, 1.08 mL cartridge**

6464F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	5	..	..	*1374.12	31.60	<sup>a</sup> Puregon 900 IU/1.08 mL [OQ]	<sup>a</sup> Recagon [OV]

▪ **FOLLITROPIN DELTA**

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

**Authority required (STREAMLINED)**

**5027**

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**follitropin delta 12 microgram/0.36 mL injection, 0.36 mL pen device**

11430N	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*445.62	31.60	Rekovele [FP]

**follitropin delta 36 microgram/1.08 mL injection, 1.08 mL pen device**

11431P	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	5	..	..	*1309.02	31.60	Rekovele [FP]

**follitropin delta 72 microgram/2.16 mL injection, 2.16 mL pen device**

11414R	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*2065.31	31.60	Rekovele [FP]

▪ **HUMAN CHORIONIC GONADOTROPHIN**

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

**Authority required (STREAMLINED)**

**6991**

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**human chorionic gonadotrophin 1500 units injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack**

12879W	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	90.76	31.60	Brevactid 1500 I.E [DZ]

**human chorionic gonadotrophin 5000 units injection [3 vials] (&) inert substance diluent [3 x 1 mL syringes], 1 pack**

12851J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	0.67	..	..	*127.09	31.60	Choriomon 5000 I.E [DZ]

▪ **HUMAN MENOPAUSAL GONADOTROPHIN**

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

**Authority required (STREAMLINED)**

**5027**

Assisted Reproductive Technology

**Clinical criteria:**

- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**human menopausal gonadotrophin 1200 units injection [1 vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack**

2038G	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*1966.23	31.60	Menopur 1200 [FP]

**human menopausal gonadotrophin 600 units injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack**

2036E	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	3	..	..	*756.51	31.60	Menopur 600 [FP]

▪ **LUTROPIN ALFA**

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

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

### Authority required (STREAMLINED)

**5251**

Stimulation of follicular development

#### Clinical criteria:

- Patient must have severe LH deficiency, **AND**
- Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### lutropin alfa 75 units injection [1 vial] (&) inert substance diluent [1 mL vial], 1 pack

10465T	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	14	..	..	*1355.47	31.60	Luveris [SG]

## SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

## PITUITARY AND HYPOTHALAMIC HORMONES AND ANALOGUES

### HYPOTHALAMIC HORMONES

#### *Gonadotropin-releasing hormones*

### NAFARELIN

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

### Authority required (STREAMLINED)

**5046**

Assisted Reproductive Technology

#### Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### nafarelin 200 microgram/actuation nasal spray, 60 actuations

5815C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*222.07	31.60	Synarel [PF]

#### *Anti-gonadotropin-releasing hormones*

### CETRORELIX

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

### Authority required (STREAMLINED)

**5046**

Assisted Reproductive Technology

#### Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### cetorelix 250 microgram injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack

9599F	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	10	..	..	*418.47	31.60	Cetrotide [SG]

### GANIRELIX

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

### Authority required (STREAMLINED)

**5046**

Assisted Reproductive Technology

#### Clinical criteria:

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### ganirelix 250 microgram/0.5 mL injection, 0.5 mL syringe

9583J	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	10	..	..	*238.47	31.60	<sup>a</sup> ARX Ganirelix [XT]	<sup>a</sup> GANIRELIX SUN [RA]
						<sup>a</sup> Orgalutran [OQ]	

**ganirelix 250 microgram/0.5 mL injection, 5 x 0.5 mL syringes**

9584K	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	2	..	..	*238.51	31.60	<sup>a</sup> ARX Ganirelix [XT] <sup>a</sup> Ganirelix Theramex [TT]	<sup>a</sup> GANIRELIX SUN [RA] <sup>a</sup> Orgalutran [OQ]

- **ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS**
- **ENDOCRINE THERAPY**
- HORMONES AND RELATED AGENTS**
- Gonadotropin releasing hormone analogues*

▪ **TRIPTORELIN**

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

**Authority required (STREAMLINED)**

**5046**

Assisted Reproductive Technology

**Clinical criteria:**

- The treatment must be for prevention of premature luteinisation and ovulation, **AND**
- Patient must be undergoing controlled ovarian stimulation, **AND**
- Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

**triptorelin acetate 100 microgram/mL injection, 7 x 1 mL syringes**

10907C	Max.Qty Packs	No. of Rpts	Premium \$	DPMQ \$	MRVSN \$	Brand Name and Manufacturer
	4	..	..	*147.99	31.60	Decapeptyl [FP]

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# Extemporaneously Prepared Benefits



# Drug Tariff

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Acacia, powdered	BP	0.04	0.36	3.24	20.59
Acetic Acid (33 per cent)	BP	0.02	0.18	1.76	17.58
Acetic Acid (6 per cent)	BP	0.01	0.04	0.41	4.11
Acetone (use as additive only)	BP	0.04	0.41	3.72	33.06
Alum	BP	0.07	0.70	6.28	55.79
Aluminium Acetate Solution	BP	0.02	0.22	2.02	17.98
Anise Water Concentrated 1 in 40	BP	0.01	0.08	0.81	8.09
Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.06	0.52	4.63
Ascorbic Acid (for use only as an ingredient of ferrous sulfate mixtures)	BP	0.14	1.39	12.47	79.16
Aspirin	BP	0.39	3.95	35.54	315.90
Belladonna Tincture	BP	0.34	3.36	30.28	269.16
Benzocaine	BP	0.29	2.87	16.39	163.90
Benzoic Acid	BP	0.22	2.23	20.03	127.16
Benzoic Acid Compound Ointment	APF	0.02	0.24	2.19	19.47
Benzoic Acid Solution	BP	0.03	0.25	2.51	25.06
Benzoin Compound Tincture	BP	0.05	0.52	4.65	41.30
Boric Acid (use as additive only)	BP	0.07	0.67	6.03	38.27
Boric Acid, Olive Oil and Zinc Oxide Ointment	QHF	0.02	0.22	2.02	12.84
Calcium Hydroxide	BP	0.28	2.77	24.94	158.34
Calcium Hydroxide Solution	BP	0.01	0.04	0.39	3.88
Castor Oil (use as additive only)	BP	0.01	0.15	1.31	11.60
Cetomacrogol Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.07	0.64	5.70
Cetrimide Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.13	1.17	10.42
Chlorhexidine Acetate (use as additive only)	BP	0.77	7.74	44.20	442.03
Chlorhexidine Aqueous Cream (for use only as a base combined with active ingredients)	APF	0.01	0.06	0.50	4.48
Chloroform (use as additive only)	BP	0.11	1.11	10.01	88.97
Chloroform Spirit	BP	0.01	0.10	0.99	9.89
Chloroform Water Concentrated 1 in 40	APF 15	0.01	0.13	1.31	13.08
Citric Acid Monohydrate	BP	0.11	1.06	9.57	60.79
Coal Tar	BP	0.06	0.55	4.99	44.33
Coal Tar Solution	BP	0.03	0.29	2.61	16.60
Cocaine Hydrochloride	BP	158.19	1581.90	9039.45	90394.50
Coconut Oil	BP	0.06	0.58	5.18	32.92
Codeine Linctus	APF	0.02	0.19	1.67	10.58
Codeine Phosphate (may only be prescribed in linctuses, mixtures or mixtures for children)	BP	8.74	87.43	499.59	4995.90
Collodion Flexible	BP	0.54	5.37	48.34	306.92
Dithranol	BP	4.17	41.73	238.48	2384.76
Emulsifying Ointment (for use only as a base combined with active ingredients)	BP	0.01	0.13	1.16	10.34
Ephedrine Hydrochloride (may only be prescribed in nasal instillations)	BP	3.03	30.27	272.41	1729.56
Ethanol (90 per cent) (use as additive only)	BP	0.01	0.06	0.51	4.56
Ethanol (96 per cent) (use as additive only)	BP	0.01	0.07	0.66	5.91
Ether Solvent (use as additive only)	BP	0.29	2.35	18.83	167.36
Eucalyptus Oil (use as additive only)	BP	0.02	0.22	1.94	17.27

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Ferrous Sulfate	BP	0.09	0.94	8.47	53.76
Formaldehyde Solution	BP	0.05	0.54	4.85	43.14
Gentian Alkaline Mixture	APF	0.01	0.09	0.68	6.00
Glycerol	BP	0.01	0.12	1.10	9.79
Honey Purified (use as additive only)	BP 1993	0.01	0.03	0.27	2.44
Hydroxybenzoate Compound Solution	APF	0.09	0.68	5.42	48.17
Iodine	BP	1.46	14.60	83.46	834.57
Iodine Alcoholic Solution	BP	0.05	0.50	4.51	28.65
Iodine Aqueous Oral Solution	BP	0.05	0.45	4.06	25.80
Kaolin Mixture	BPC 1968	0.04	0.39	3.47	30.80
Kaolin and Opium Mixture	APF 14	0.01	0.10	0.82	7.27
Lactic Acid	BP	0.35	3.51	31.63	200.83
Lavender Spike Oil	BPC 1968	0.13	1.29	11.57	73.44
Liquorice Liquid Extract	BP	0.19	1.85	16.69	148.40
Magnesium Carbonate Light	BP	0.05	0.37	2.92	25.99
Magnesium Sulfate (may only be prescribed for other than oral use)	BP	0.01	0.10	0.94	8.33
Magnesium Trisilicate	BP	0.06	0.61	5.53	49.14
Menthol, Racemic or Levomenthol	BP	0.29	2.94	26.49	168.16
Methyl Hydroxybenzoate	BP	0.52	5.17	46.49	295.16
Methyl Hydroxybenzoate Solution	APF	0.05	0.53	5.31	53.13
Methylated Industrial Spirit (use as additive only)	BP	0.01	0.01	0.11	0.95
Olive Oil (use as additive only)	BP	0.01	0.10	0.94	8.34
Paraffin Hard	BP	0.07	0.75	6.73	59.83
Paraffin Light Liquid	BP	0.01	0.14	1.28	8.13
Paraffin Liquid (use as additive only)	BP	0.01	0.10	0.94	8.39
Paraffin Soft White	BP	0.01	0.08	0.74	6.53
Peppermint Oil (use as additive only)	BP	0.10	1.02	9.14	58.00
Peppermint Water Concentrated 1 in 40 (use as additive only)	APF 16	0.05	0.46	4.10	36.48
Phenobarbitone Sodium (may only be prescribed for the treatment of epilepsy)	BP	1.47	14.69	132.17	839.16
Phenol Liquefied (not available for ear drops)	BP	0.46	4.60	41.39	262.77
Podophyllum Resin	BP	9.07	90.74	518.49	5184.90
Potassium Citrate	BP	0.03	0.34	3.10	27.58
Potassium Iodide	BP	0.58	5.78	52.06	330.54
Potassium Permanganate	BP	0.07	0.67	6.07	53.95
Propyl Hydroxybenzoate	BP	0.46	4.61	41.45	263.16
Propylene Glycol	BP	0.03	0.32	2.87	18.25
Resorcinol	BP	0.45	3.57	28.59	254.15
Salicylic Acid	BP	0.06	0.59	5.33	33.82
Salicylic Acid Ointment	APF	0.02	0.17	1.38	12.23
Salicylic Acid Ointment	BP	0.02	0.17	1.38	12.23
Simple Ointment (white) (for use only as a base combined with active ingredients)	BP	0.02	0.20	1.82	16.15
Simple Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.14	1.11	9.88
Sodium Bicarbonate	BP	0.04	0.36	3.23	28.74
Sodium Chloride	BP	0.03	0.30	2.69	23.88
Sodium Chloride Solution	BP	0.01	0.01	0.14	1.38
Sodium Citrate	BP	0.06	0.57	5.13	32.54
Sodium Thiosulfate (use as additive only)	BP	0.09	0.92	8.30	73.76
Starch	BP	0.02	0.23	2.03	18.05
Sulfur Ointment (for use only as a base combined with active ingredients)	BP 1980	0.02	0.17	1.72	17.21
Sulfur Precipitated	BP 1980	0.03	0.30	2.68	17.00
Syrup	BP	0.01	0.07	0.60	5.30
Talc Purified, sterilised	BP	6.35	63.49	571.39	5079.04
Thymol	BP	0.59	5.94	53.42	339.16
Thymol Compound Mouth Wash	APF 15	0.01	0.11	0.95	8.42
Tragacanth Compound Powder	BP 1980	0.07	0.57	4.58	40.73
Tragacanth Mucilage	APF 13	0.01	0.11	1.13	11.27
Tragacanth Mucilage	BPC 1973	0.01	0.11	1.06	10.55
Tragacanth, powdered	BP	0.74	7.38	66.45	421.89
Trichloroacetic Acid	BP 1980	0.33	3.26	29.33	186.24

Drug	Standard	Recovery Prices			
		0.1 g/mL \$	1 g/mL \$	10 g/mL \$	100 g/mL \$
Triethanolamine	BP	0.18	1.78	15.98	101.46
Water For Injections, sterilised (b) (extemporaneously prepared eye drops and eye lotions)	BP	0.00	0.00	11.42	11.42
Water Purified	BP	0.01	0.01	0.13	1.12
Wool Alcohols Ointment (white) (for use only as a base combined with active ingredients)	BP	0.03	0.21	1.64	14.55
Wool Alcohols Ointment (yellow) (for use only as a base combined with active ingredients)	BP	0.02	0.19	1.48	13.18
Wool Fat	BP	0.05	0.48	4.31	38.35
Wool Fat Hydrous	BP	0.03	0.30	2.68	23.78
Zinc Compound Paste	BP	0.05	0.48	4.36	38.78
Zinc Cream (for use only as a base combined with active ingredients)	BP	0.02	0.22	2.02	17.94
Zinc Oxide	BP	0.05	0.53	4.78	42.47
Zinc Sulfate	BP	0.09	0.87	7.84	49.78
Zinc and Salicylic Acid Paste	BP	0.04	0.37	3.36	29.86

# Container Prices

Type	Container	Price \$
Dispensing Bottles	25mL	1.74
Dispensing Bottles	50mL	0.73
Dispensing Bottles	100mL	0.87
Dispensing Bottles	200mL	0.96
Dispensing Bottles	500mL	1.28
Poison Bottles	25mL	1.21
Poison Bottles	50mL	1.30
Poison Bottles	100mL	1.36
Poison Bottles	200mL	1.48
Poison Bottles	500mL	2.00
Poison Bottles	600mL	4.05
Poison Bottles	1000mL	3.99
Dropper Containers (Glass)	15mL	1.67
Dropper Containers (Polythene)	15mL	0.98
Screw Cap Jars	25g	0.65
Screw Cap Jars	50g	1.36
Screw Cap Jars	100g	1.38
Screw Cap Jars	200g	0.77
Screw Cap Jars	500g	2.19
Screw Cap Jars	1000g	4.39

# Standard Formula Preparations

Code	Item	Reference	DPMQ \$	MRVSN \$
	<b>Creams</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7502W	Salicylic Acid and Sulfur Aqueous	APF	18.31	20.18
	<b>Ear Drops</b>			
	<b>(Maximum Quantity 15 ml and 2 Repeats)</b>			
7643G	Aluminium Acetate	BP	14.72	16.59
7642F	Aluminium Acetate	APF	13.59	15.46
7314Y	Sodium Bicarbonate	APF & BP	12.63	14.50
7313X	Spirit	APF	12.17	14.04
	<b>Inhalations</b>			
	<b>(Maximum Quantity 50 ml and 1 Repeat)</b>			
7484X	Benzoin and Menthol	APF	37.72	31.60
7308P	Menthol	APF	17.47	19.34
7310R	Menthol and Eucalyptus	BP1980	18.23	20.10
	<b>Linctuses containing Codeine Phosphate</b>			
	<b>(Maximum Quantity 100 ml and 0 Repeat)</b>			
7530H	Codeine	APF	22.16	24.03
	<b>Lotions</b>			
	<b>(Maximum Quantity 200 ml and 2 Repeats)</b>			
7709R	Aluminium Acetate Aqueous	APF	16.34	18.21
	<b>Mixtures, Other</b>			
	<b>(Maximum Quantity 200 ml and 4 Repeats)</b>			
7348R	Kaolin	BPC 1968	55.67	31.60
7342K	Magnesium Trisilicate	BPC 1968	28.93	30.80
7343L	Magnesium Trisilicate and Belladonna	BPC 1968	45.58	31.60
	<b>Ointments, Waxes</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7914M	Benzoic Acid Compound	APF & BP	31.56	31.60
7902X	Boric Acid, Olive Oil and Zinc Oxide	QHF	24.93	26.80
7926E	Salicylic Acid	APF	25.12	26.99
7928G	Salicylic Acid (extemporaneous formula)	BP	25.12	26.99
	<b>Paints</b>			
	<b>(Maximum Quantity 25 ml and 1 Repeat)</b>			
7567G	Podophyllin Compound	APF 16 & BP	362.05	31.60
7568H	Salicylic Acid	APF	122.16	31.60
	<b>Pastes, Other</b>			
	<b>(Maximum Quantity 100 g and 1 Repeat)</b>			
7558T	Zinc	APF & BP	50.87	31.60
	<b>Powders for Internal Use</b>			
	<b>(Maximum Quantity 100 g and 2 Repeats)</b>			
7545D	Magnesium Trisilicate	BP	60.62	31.60

# Codes, Maximum Quantities, and Number of Repeats for Extemporaneously Prepared Benefits

Code	Preparation	Maximum Quantity	Number of Repeats
13Q	Creams	100 g	1
48M	Dusting Powders	100 g	1
15T	Ear Drops	15 ml	2
19B	Eye Drops containing Cocaine Hydrochloride	15 ml	..
22E	Eye Drops, Other	15 ml	5
23F	Eye Lotions	200 ml	2
29M	Inhalations	50 ml	1
64J	Linctuses containing Codeine Phosphate	100 ml	..
34T	Linctuses, Other	100 ml	2
39C	Lotions	200 ml	2
65K	Mixtures containing Codeine Phosphate	200 ml	..
66L	Mixtures for Children containing Codeine Phosphate	100 ml	..
41E	Mixtures for Children, Other	100 ml	4
40D	Mixtures, Other	200 ml	4
30N	Mouth Washes	200 ml	1
42F	Nasal Instillations	15 ml	2
43G	Ointments, Waxes	100 g	1
44H	Paints	25 ml	1
63H	Pastes containing Cocaine Hydrochloride	25 g	..
45J	Pastes, Other	100 g	1
49N	Powders for Internal Use	100 g	2
52R	Solutions	200 ml	2

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# Index of Manufacturers Codes

<b>Code</b>	<b>Manufacturer</b>	<b>Code</b>	<b>Manufacturer</b>
<b>AB</b>	Abbott Australasia Pty Ltd	<b>IB</b>	Apotex Pty Ltd
<b>AE</b>	AFT Pharmaceuticals (AU) Pty Ltd	<b>IE</b>	BeiGene AUS Pty Ltd
<b>AF</b>	Alphapharm Pty Ltd	<b>IG</b>	Sigma Company Limited
<b>AL</b>	Alphapharm Pty Ltd	<b>IL</b>	iNova Pharmaceuticals (Australia) Pty Limited
<b>AN</b>	Amgen Australia Pty Limited	<b>IM</b>	iNova Pharmaceuticals (Australia) Pty Limited
<b>AP</b>	AstraZeneca Pty Ltd	<b>IO</b>	BioMarin Pharmaceutical Australia Pty Ltd
<b>AQ</b>	Alcon Laboratories (Australia) Pty Ltd	<b>IQ</b>	Alcon Laboratories (Australia) Pty Ltd
<b>AS</b>	Aspen Pharmacare Australia Pty Limited	<b>IR</b>	Indivior Pty Ltd
<b>AV</b>	sanofi-aventis Australia Pty Ltd	<b>IS</b>	Ipsen Pty Ltd
<b>BB</b>	Blackmores Limited	<b>IT</b>	InterPharma Pty Ltd
<b>BD</b>	Biogen Australia Pty Ltd	<b>IU</b>	AUPHARMA PTY LTD
<b>BE</b>	Beiersdorf Australia Ltd	<b>IX</b>	Clinect Pty Ltd
<b>BG</b>	Sandoz Pty Ltd	<b>IY</b>	Clinect Pty Ltd
<b>BN</b>	Bayer Australia Ltd	<b>JA</b>	JAZZ PHARMACEUTICALS ANZ PTY LTD
<b>BQ</b>	Bristol-Myers Squibb Australia Pty Ltd	<b>JC</b>	Janssen-Cilag Pty Ltd
<b>BR</b>	B. Braun Australia Pty Ltd	<b>JJ</b>	Johnson & Johnson Medical Pty Ltd
<b>BV</b>	BSN medical (Aust.) Pty Ltd	<b>JM</b>	Glenmark Pharmaceuticals (Australia) Pty Ltd
<b>BX</b>	BAXTER HEALTHCARE PTY LTD	<b>JO</b>	Juno Pharmaceuticals Pty Ltd
<b>BY</b>	Boehringer Ingelheim Pty Ltd	<b>JT</b>	Johnson & Johnson Pacific Pty Limited
<b>BZ</b>	Boucher & Muir Pty Ltd	<b>JU</b>	Juno Pharmaceuticals Pty Ltd
<b>CC</b>	ConvaTec Australia Pty Ltd	<b>JX</b>	Juno Pharmaceuticals Pty Ltd
<b>CF</b>	CNS Pharma Pty Ltd	<b>JZ</b>	Juniper Biologics Pty Ltd
<b>CR</b>	Pharmacor Pty Limited	<b>KE</b>	Kendall Australasia Pty Ltd
<b>CS</b>	Seqirus (Australia) Pty Ltd	<b>KI</b>	KCI Medical Australia Pty Ltd
<b>CT</b>	Coloplast Pty Ltd	<b>KO</b>	KYOWA KIRIN AUSTRALIA PTY LTD
<b>CU</b>	Care Pharmaceuticals Pty Limited	<b>KP</b>	Eli Lilly Australia Pty Ltd
<b>CX</b>	Contact Lens Centre Australia Limited	<b>KQ</b>	PHERO PHARMA PTY LTD
<b>DE</b>	Stallergenes Australia Pty Ltd	<b>KY</b>	Key Pharmaceuticals Pty Ltd
<b>DJ</b>	De Fries Industries Pty Ltd	<b>LC</b>	Lohmann & Rauscher Pty Ltd
<b>DQ</b>	Church & Dwight (Australia) Pty Ltd	<b>LG</b>	Leo Pharma Pty Ltd
<b>DV</b>	Medical Developments International Limited	<b>LL</b>	Astellas Pharma Australia Pty Ltd
<b>DX</b>	Ascensia Diabetes Care Australia Pty Limited	<b>LM</b>	Link Medical Products Pty Ltd
<b>DZ</b>	Medsurge Healthcare Pty Ltd	<b>LN</b>	Aspen Pharmacare Australia Pty Limited
<b>EI</b>	Eisai Australia Pty Ltd	<b>LO</b>	Leo Pharma Pty Ltd
<b>EJ</b>	Encapsulate Pharma Pty Ltd	<b>LQ</b>	Astellas Pharma Australia Pty Ltd
<b>EO</b>	Ego Pharmaceuticals Pty Ltd	<b>LR</b>	Cipla Australia Pty Ltd
<b>EU</b>	Chiesi Australia Pty Ltd	<b>LS</b>	Astellas Pharma Australia Pty Ltd
<b>EV</b>	Teva Pharma Australia Pty Ltd	<b>LT</b>	Aspen Pharmacare Australia Pty Limited
<b>EW</b>	Celltrion Healthcare Australia Pty Ltd	<b>LU</b>	Lundbeck Australia Pty Ltd
<b>FB</b>	Pierre Fabre Australia Pty Ltd	<b>LX</b>	Lawley Pharmaceuticals Pty Ltd
<b>FD</b>	Dr Falk Pharma Australia Pty Ltd	<b>LY</b>	Eli Lilly Australia Pty Ltd
<b>FF</b>	Phebra Pty Ltd	<b>MF</b>	Mundipharma Pty Limited
<b>FG</b>	Phebra Pty Ltd	<b>MH</b>	Molnlycke Health Care Pty Ltd
<b>FI</b>	Boehringer Ingelheim Pty Ltd	<b>MK</b>	Merck Sharp & Dohme (Australia) Pty Ltd
<b>FJ</b>	Pharmaco (Australia) Limited	<b>MM</b>	3M Pharmaceuticals Australia Pty Ltd
<b>FK</b>	A.Menarini Australia Pty Limited	<b>MQ</b>	Alphapharm Pty Ltd
<b>FP</b>	Ferring Pharmaceuticals Pty Limited	<b>MT</b>	Mentholatum Australasia Pty Ltd
<b>FQ</b>	Pharmaco (Australia) Limited	<b>MW</b>	Biomed Aust Pty Limited
<b>FT</b>	AMICUS THERAPEUTICS PTY LTD	<b>NB</b>	Nova Pharmaceuticals Australasia Pty Ltd
<b>FX</b>	Gedeon Richter Australia Pty Ltd	<b>NE</b>	Norgine Pty. Ltd.
<b>FZ</b>	Pfizer Australia Pty Ltd	<b>NF</b>	Novo Nordisk Pharmaceuticals Pty. Limited
<b>GA</b>	Galderma Australia Pty Ltd	<b>NG</b>	NEON HEALTHCARE PTY LIMITED
<b>GC</b>	GlaxoSmithKline Australia Pty Ltd	<b>NM</b>	Novartis Pharmaceuticals Australia Pty Limited
<b>GH</b>	Amdipharm Mercury (Australia) Pty Limited	<b>NO</b>	Novo Nordisk Pharmaceuticals Pty. Limited
<b>GI</b>	Gilead Sciences Pty Limited	<b>NP</b>	NICE-PAK PRODUCTS PTY. LTD.
<b>GJ</b>	HALEON AUSTRALIA PTY LTD	<b>NQ</b>	Takeda Pharmaceuticals Australia Pty. Ltd.
<b>GK</b>	GlaxoSmithKline Australia Pty Ltd	<b>NT</b>	Nestle Australia Ltd
<b>GN</b>	Actavis Pty Ltd	<b>NU</b>	Nutricia Australia Pty Limited
<b>GO</b>	Viatrix Pty Ltd	<b>NV</b>	Novartis Pharmaceuticals Australia Pty Limited
<b>GQ</b>	Generic Health Pty Ltd	<b>OB</b>	Oral B Laboratories Pty Ltd
<b>GT</b>	Viatrix Pty Ltd	<b>OC</b>	Accord Healthcare Pty. Ltd.
<b>GX</b>	Apotex Pty Ltd	<b>OH</b>	Orpharma Pty Ltd
<b>GZ</b>	sanofi-aventis Australia Pty Ltd	<b>OJ</b>	The Trustee for ORSPEC PHARMA UNIT TRUST
<b>HB</b>	Besins Healthcare Australia Pty Ltd	<b>OM</b>	Colgate Oral Care
<b>HQ</b>	Generic Health Pty Ltd	<b>ON</b>	Orion Laboratories Pty. Ltd.
<b>HR</b>	Paul Hartmann Pty Ltd	<b>OQ</b>	Organon Pharma Pty Ltd
<b>HT</b>	BTC Speciality Health Pty Ltd	<b>OS</b>	Otsuka Australia Pharmaceutical Pty. Ltd
<b>HW</b>	HAMELN PHARMA PTY. LTD.	<b>OU</b>	Oraderm Pharmaceuticals Pty Ltd
<b>HX</b>	Sandoz Pty Ltd	<b>OV</b>	Organon Pharma Pty Ltd



<b>Code</b>	<b>Manufacturer</b>	<b>Code</b>	<b>Manufacturer</b>
<b>OW</b>	Arrow Pharma Pty Ltd	<b>XH</b>	MS Health Pty Ltd
<b>OX</b>	Orion Pharma (Aus) Pty Limited	<b>XI</b>	Alexion Pharmaceuticals Australasia Pty Ltd
<b>PB</b>	Pharmaco (Australia) Limited	<b>XN</b>	Southern XP Pty Ltd
<b>PF</b>	Pfizer Australia Pty Ltd	<b>XO</b>	Echo Therapeutics Pty Ltd
<b>PK</b>	Fresenius Kabi Australia Pty Limited	<b>XT</b>	Arrotex Pharmaceuticals Pty Ltd
<b>PP</b>	Petrus Pharmaceuticals Pty Ltd	<b>XW</b>	Arrotex Pharmaceuticals Pty Ltd
<b>PY</b>	Procter & Gamble Pharmaceuticals Australia Pty Ltd	<b>XY</b>	MAXX PHARMA PTY LTD
<b>QH</b>	Cortex Health Pty Ltd	<b>YG</b>	EUGIA PHARMA (AUSTRALIA) PTY LTD
<b>QS</b>	Sandoz Pty Ltd	<b>YN</b>	Mayne Pharma International Pty Ltd
<b>QY</b>	Pro Pharmaceuticals Group Pty. Ltd.	<b>YO</b>	The Trustee for ORSPEC PHARMA UNIT TRUST
<b>RA</b>	Sun Pharma ANZ Pty Ltd	<b>YT</b>	Mayne Products Pty Ltd
<b>RB</b>	Bio Revive Pty Ltd	<b>ZB</b>	Specialised Therapeutics Pm Pty Ltd
<b>RC</b>	Reckitt Benckiser (Australia) Pty Limited	<b>ZE</b>	Seekwell Pty Ltd
<b>RF</b>	Arrow Pharma Pty Ltd	<b>ZO</b>	Swedish Orphan Biovitrum Pty Ltd
<b>RI</b>	Dr Reddy's Laboratories (Australia) Pty Ltd	<b>ZS</b>	Strides Pharma Science Pty Ltd
<b>RJ</b>	Recordati Rare Diseases Australia Pty. Ltd.	<b>ZU</b>	Seekwell Pty Ltd
<b>RM</b>	Pharmacor Pty Limited		
<b>RN</b>	Sun Pharma ANZ Pty Ltd		
<b>RO</b>	Roche Products Pty Ltd		
<b>RQ</b>	Reach Pharmaceuticals Pty Ltd		
<b>RW</b>	Arrow Pharma Pty Ltd		
<b>RX</b>	Servier Laboratories (Aust.) Pty. Ltd.		
<b>RZ</b>	Dr Reddy's Laboratories (Australia) Pty Ltd		
<b>SA</b>	SciGen (Australia) Pty Limited		
<b>SB</b>	Nutricia Australia Pty Limited		
<b>SE</b>	Servier Laboratories (Aust.) Pty. Ltd.		
<b>SG</b>	Merck Healthcare Pty Ltd		
<b>SI</b>	Sigma Company Limited		
<b>SN</b>	Smith & Nephew Pty Limited		
<b>SS</b>	SSL Australia Pty Ltd		
<b>SW</b>	sanofi-aventis Australia Pty Ltd		
<b>SY</b>	Bayer Australia Ltd		
<b>SZ</b>	Sandoz Pty Ltd		
<b>TB</b>	Teva Pharma Australia Pty Ltd		
<b>TD</b>	STADA Pharmaceuticals Australia Pty Limited		
<b>TF</b>	Te Arai BioFarma Limited		
<b>TG</b>	ANTENGENE (AUS) PTY. LTD.		
<b>TJ</b>	Taiho Pharma Oceania Pty Ltd		
<b>TK</b>	Takeda Pharmaceuticals Australia Pty. Ltd.		
<b>TN</b>	Medtas Pty Ltd		
<b>TQ</b>	Terumo BCT Australia Pty Limited		
<b>TT</b>	Theramex Australia Pty Ltd		
<b>TW</b>	Apotex Pty Ltd		
<b>TX</b>	Apotex Pty Ltd		
<b>TY</b>	Apotex Pty Ltd		
<b>UC</b>	UCB Australia Proprietary Limited		
<b>UG</b>	Urgo Medical Australia Pty Ltd		
<b>UI</b>	PERRIGO AUSTRALIA PTY LIMITED		
<b>UJ</b>	Upjohn Australia Pty Ltd		
<b>UL</b>	Bausch & Lomb (Australia) Pty Ltd		
<b>UM</b>	Unomedical Pty Ltd		
<b>UN</b>	Unilever Australia Limited		
<b>UO</b>	Bausch & Lomb (Australia) Pty Ltd		
<b>UR</b>	Camurus Pty Ltd		
<b>VB</b>	AbbVie Pty Ltd		
<b>VE</b>	AbbVie Pty Ltd		
<b>VF</b>	VitaFlo Australia Pty Limited		
<b>VI</b>	ViiV Healthcare Pty Ltd		
<b>VL</b>	Vifor Pharma Pty Limited		
<b>VO</b>	Avallon Pharmaceuticals Pty Limited		
<b>VQ</b>	Novartis Pharmaceuticals Australia Pty Limited		
<b>VR</b>	Vertex Pharmaceuticals (Australia) Pty. Ltd.		
<b>VZ</b>	Sanofi-aventis Healthcare Pty Ltd		
<b>WA</b>	sanofi-aventis Australia Pty Ltd		
<b>WG</b>	WAGNER PHARMACEUTICALS PTY LTD		
<b>WM</b>	MEDISON PHARMA AUSTRALIA PTY LIMITED		
<b>WZ</b>	Bridgewest Perth Pharma Pty Ltd		
<b>XC</b>	Southern Cross Pharma Pty Ltd		
<b>XE</b>	ACCELAGEN PTY LTD		

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